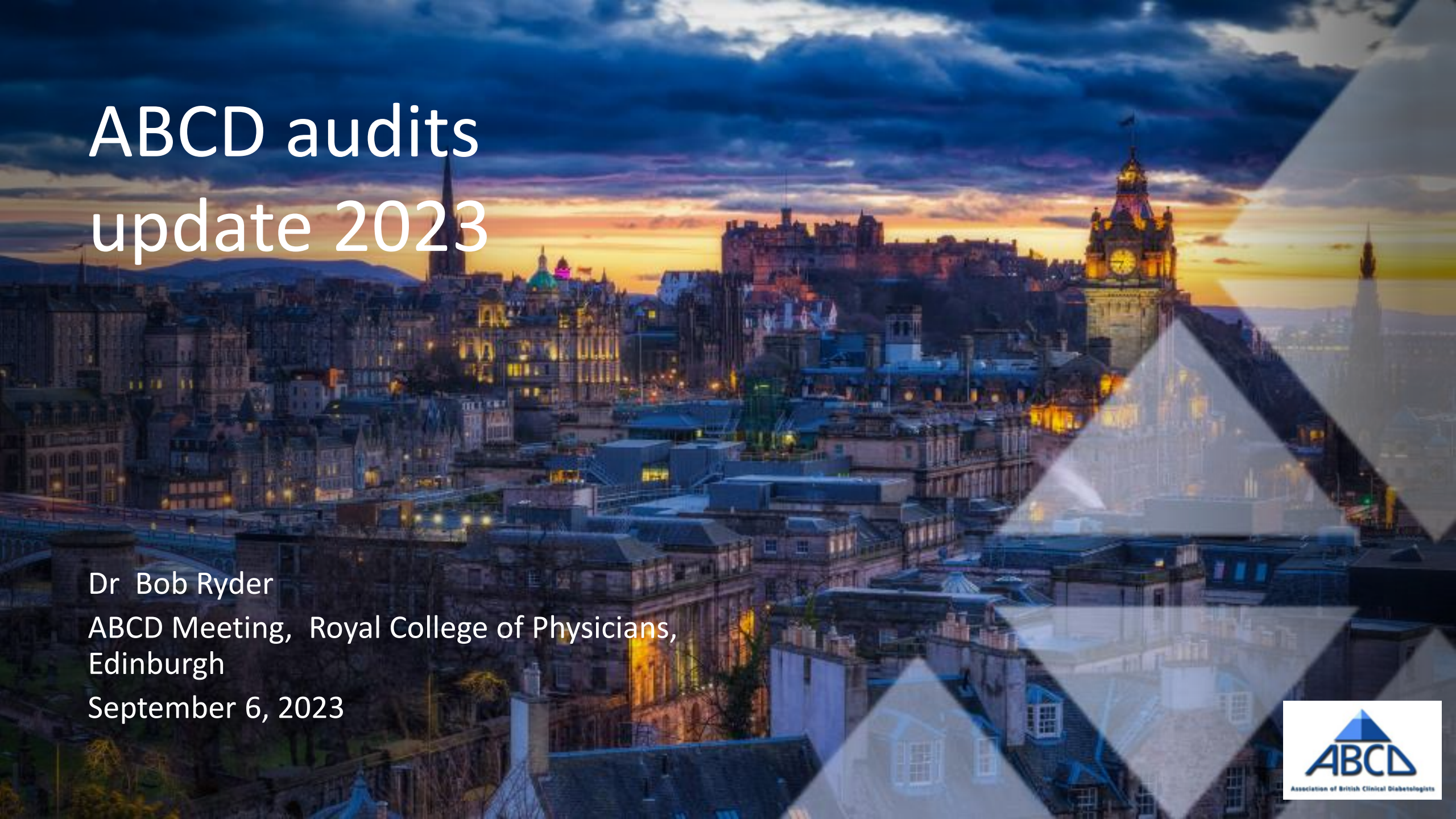
ABCD audits update 2023



Dr Bob Ryder

ABCD Meeting, Royal College of Physicians, Edinburgh

September 6, 2023

Prologue

- An Aid to the MRCP PACES – please help

PACES23

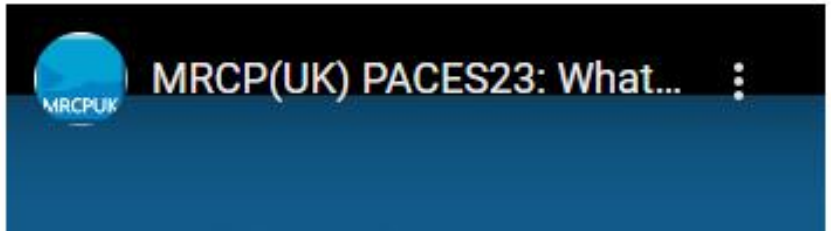
FAQs
Part 1
Part 2
PACES
News
Exam dates and fees
Centre locations
How to apply
Format
Exam day
Preparation
Sample scenarios

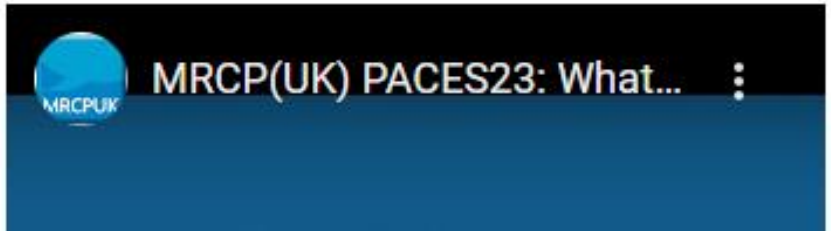
We are pleased to confirm that the new format examination, now known as PACES23 will be introduced from the third Diet of 2023*

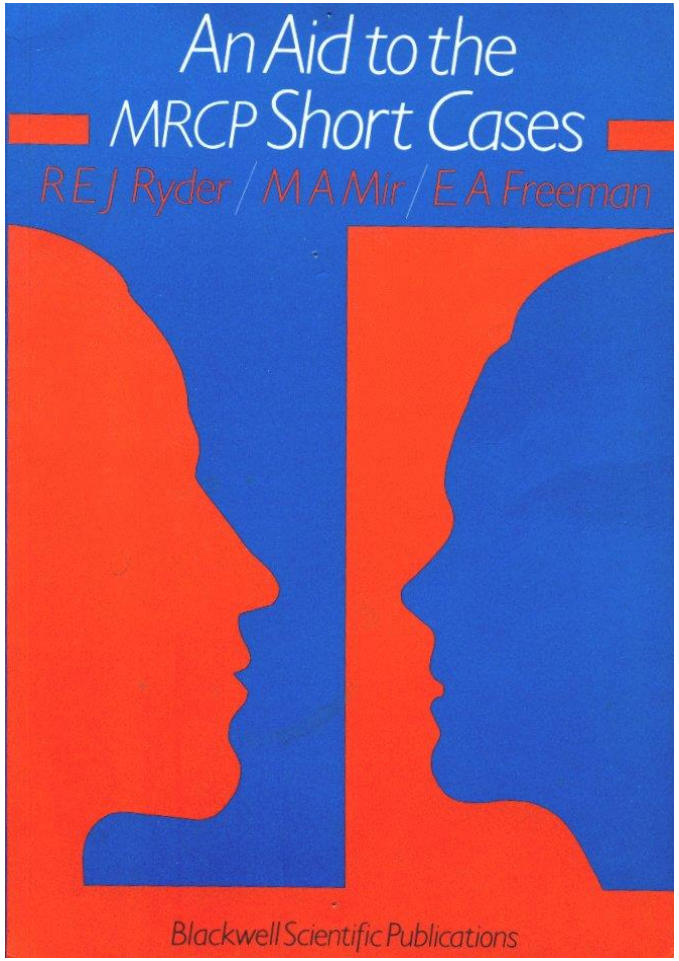
The examination will still test the same clinical skills, and there will still be five stations. However, some of the encounters are changing. We will be providing more information and training materials for candidates and examiners in the lead up to introduction of PACES23. Further updates will be available here on this webpage in due course.

*PACES23 will be introduced for candidates sitting in Singapore from early 2024.

Below are videos from Dr Stuart Hood, Associate Medical Director for Clinical Examinations. In these videos, he talks about PACES23 - what the changes are and what will remain the same.



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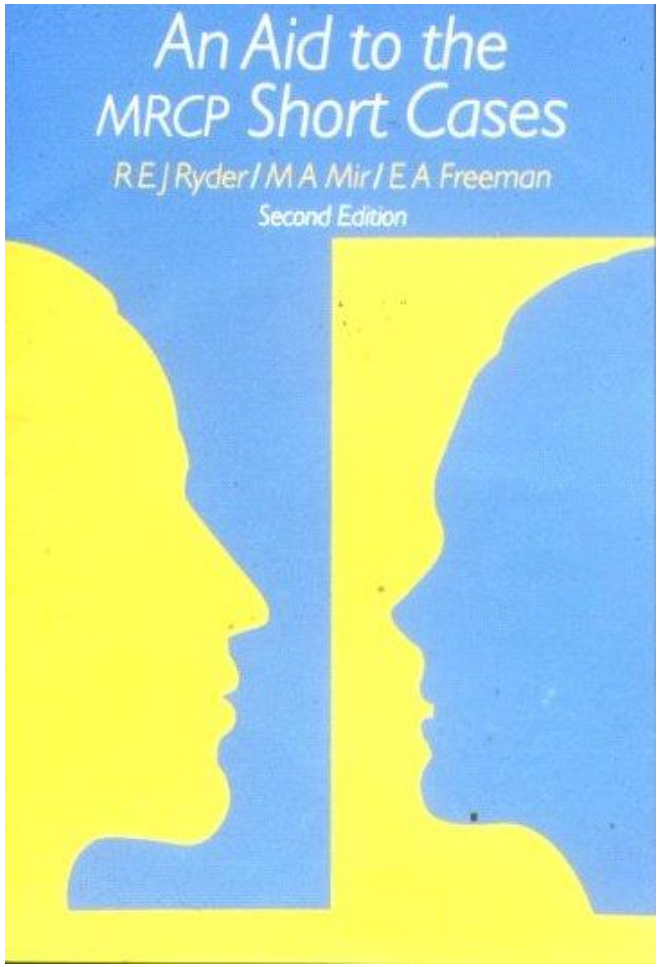
MRCP Short Cases
R E J Ryder / M A Mir / E A Freeman
Blackwell Scientific Publications

1986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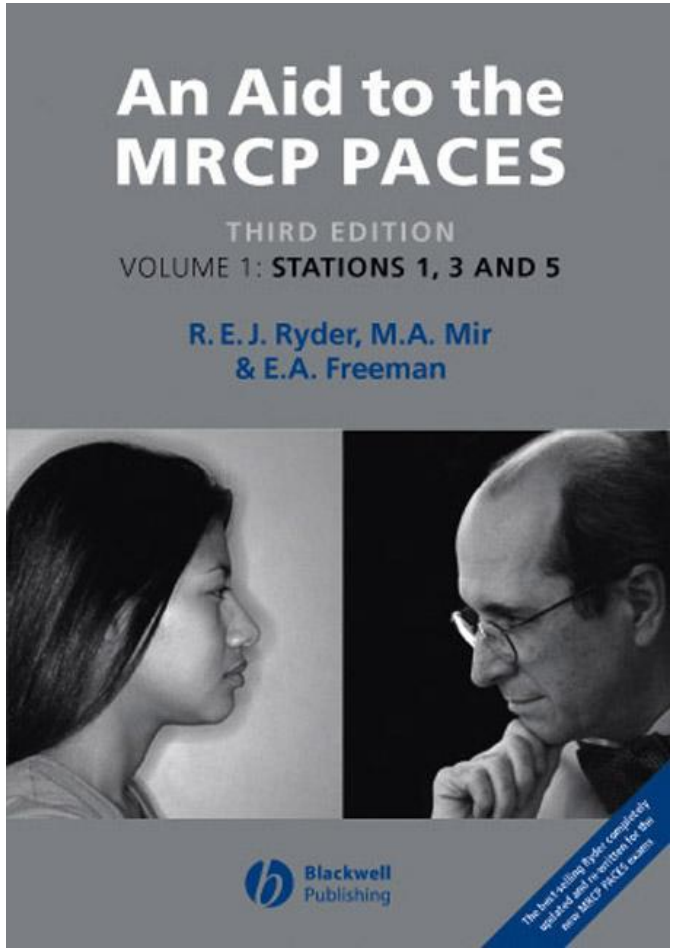
Second Edition

1999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VOLUME 1: STATIONS 1, 3 AND 5
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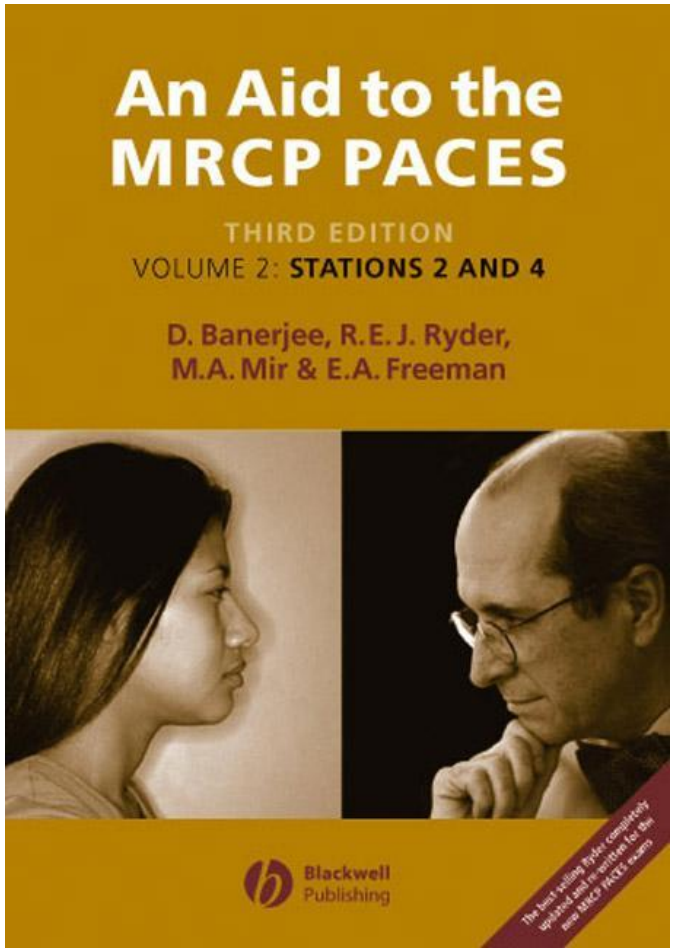
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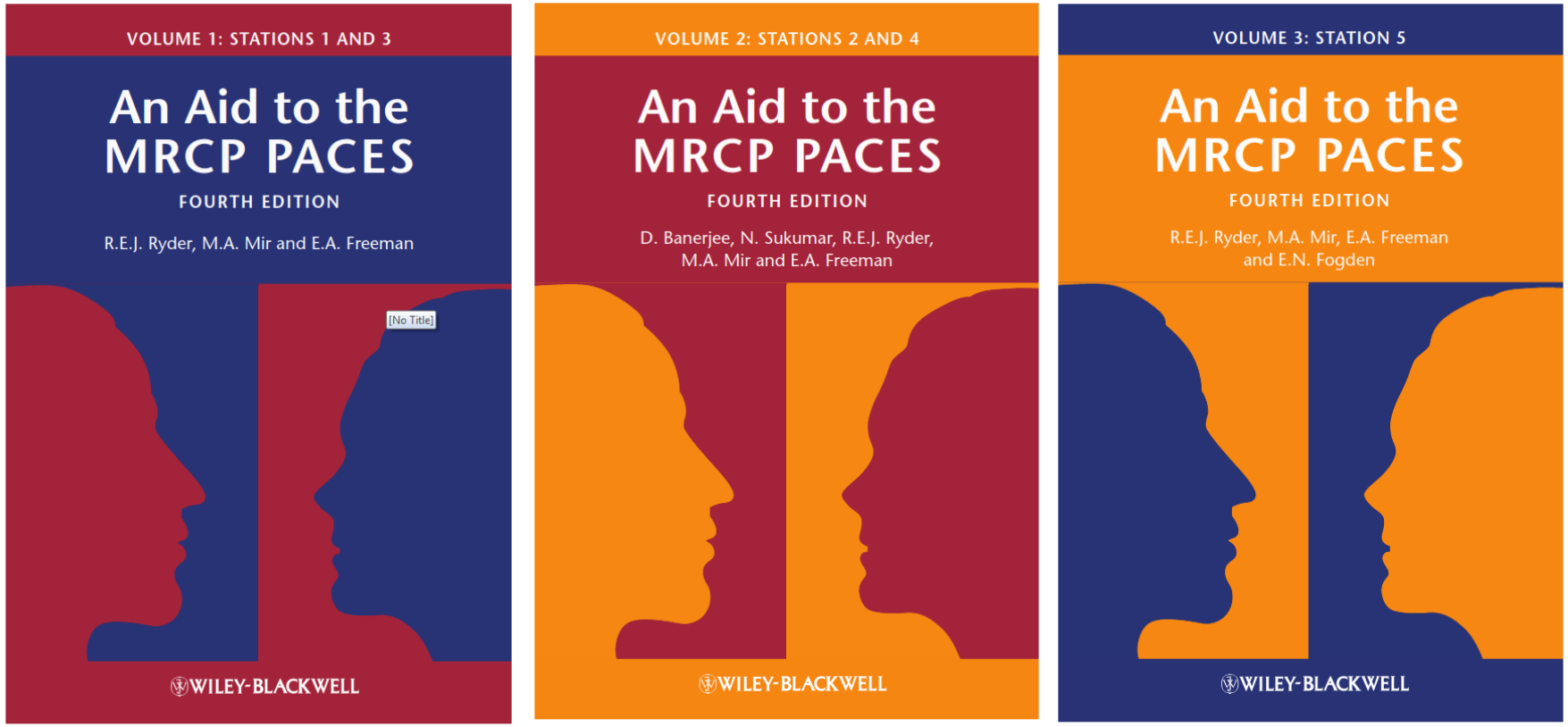
Blackwell Publishing

2003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An Aid to the MRCP PACES
FOURTH EDITION
R.E.J. Ryder, M.A. Mir and E.A. Freeman
[No Title]
WILEY-BLACKWELL
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An Aid to the MRCP PACES
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D. Banerjee, N. Sukumar, R.E.J. Ryder, M.A. Mir and E.A. Freeman
WILEY-BLACKWELL
VOLUME 3: STATION 5
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R.E.J. Ryder, M.A. Mir, E.A. Freeman and E.N. Fogden
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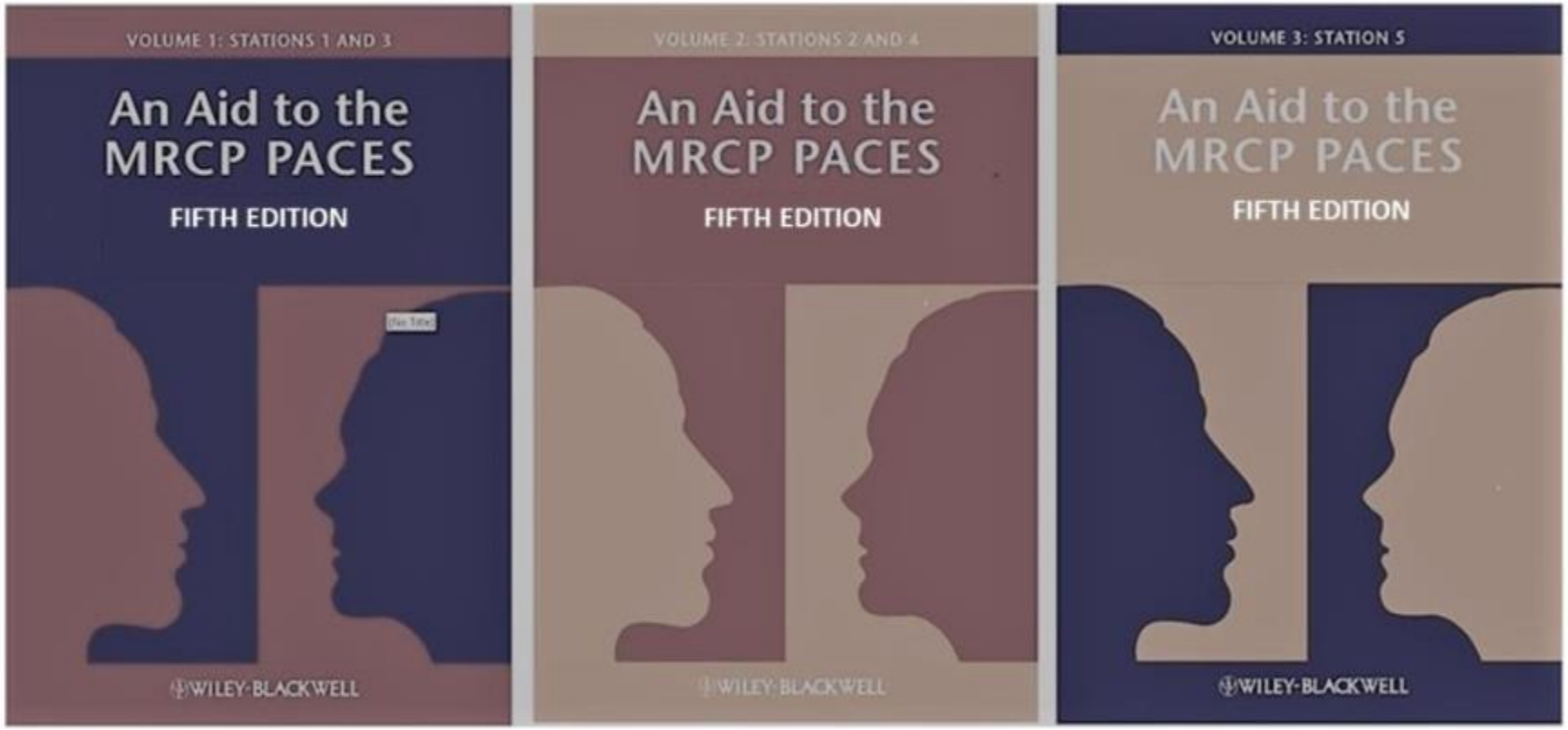
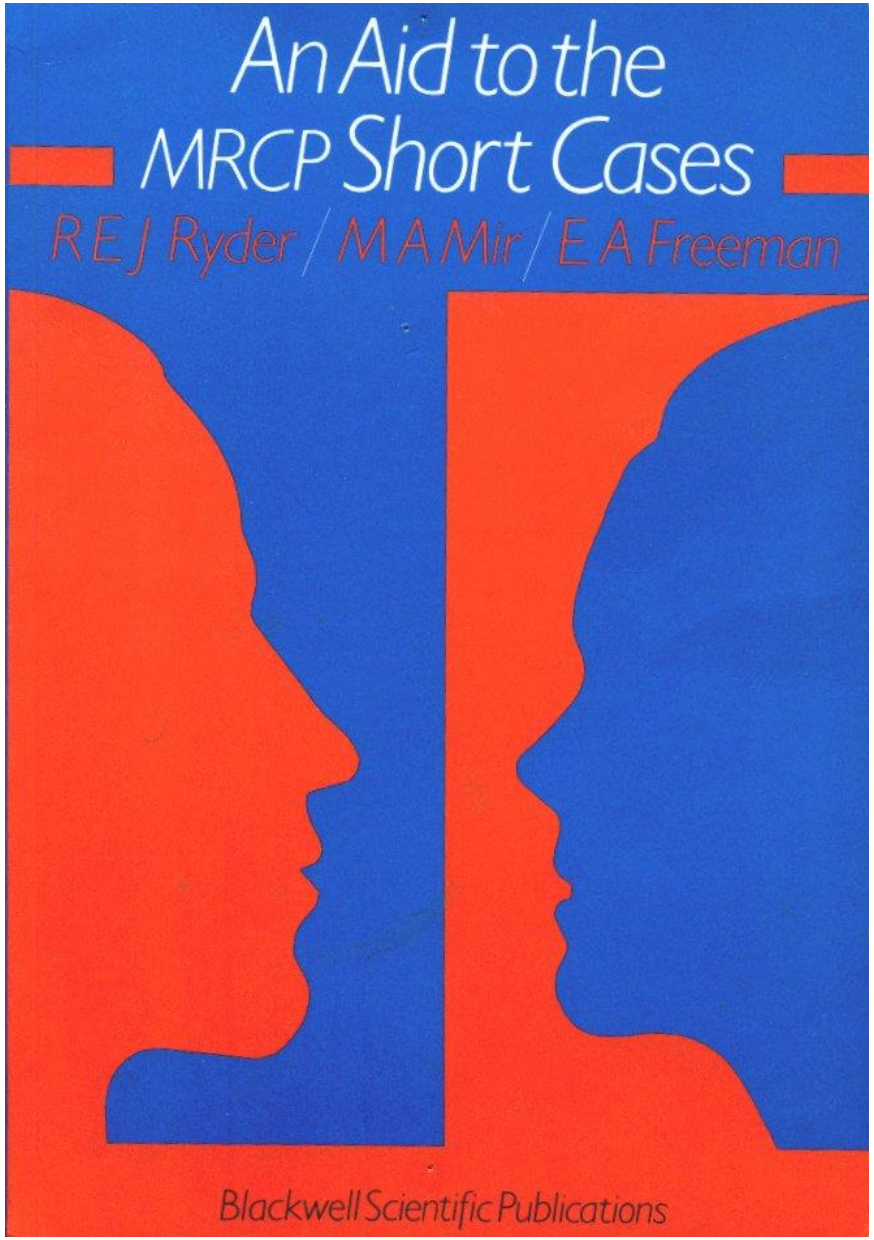
2012-2013

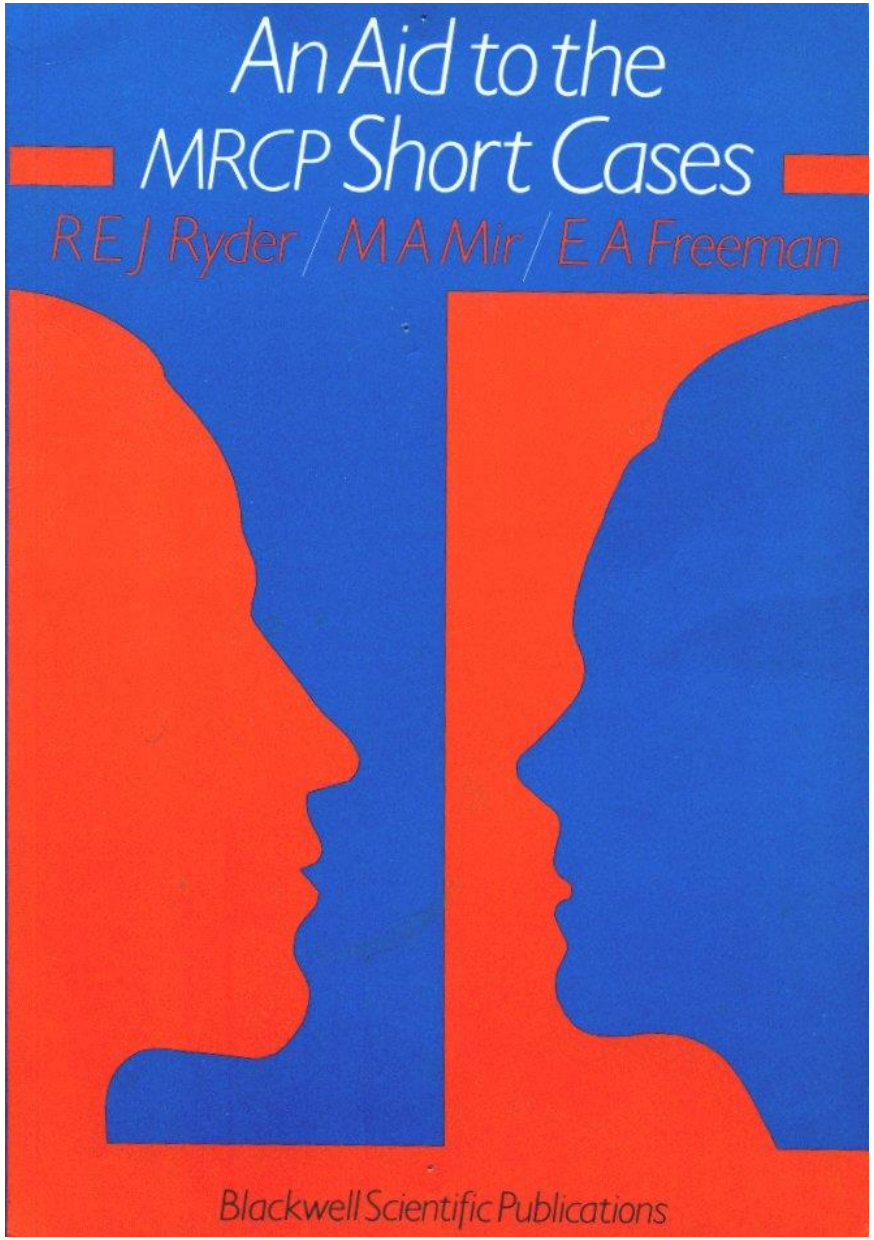


In production - 2024



Section 4
Experiences, Anecdotes, Tips, Facts and Figures, Quotations

*'I know 'cos I was there'**



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Prologue

- An Aid to the MRCP PACES – please help
- Please ask your juniors sitting PACES from this autumn onwards to go to:
- https://ryder-mrcp.org.uk/
- Tell us about their experience no matter whether they pass/fail/have a terrible time etc etc

Prologue

- An Aid to the MRCP PACES – please help
- Please ask your juniors sitting PACES from this autumn onwards to go to:
- https://ryder-mrcp.org.uk/
- Tell us about their experience no matter whether they pass/fail/have a terrible time etc etc
- Tell them Dr Ryder is asking them to help!

Prologue 2

- ABCD audits – Scottish project
- If any of you work in Scotland, you may be able to contribute significantly to the audit programme with very little work by yourself and your name on abstracts and papers!
- Contact me at bob.ryder@nhs.net or see me after/during lunch

Prologue 3

QiC Diabetes Voting 2023

Vote for Diabetes Professional

Vote for Outstanding Educator in Diabetes

Vote for the People's Award

Vote here

QiC Diabetes Awards 2023 - Nominate your Diabetes Hero

Categories for nomination:

Diabetes Professional of the Year - Quality In Care

The People's Award

QiC Diabetes Awards 2023 – Open for entry

Entry deadline – 7th July 2023

QiC Diabetes 2023 – Enter now

Download the entry kit

QiC Diabetes Awards 2023

Launching 2023 QiC Diabetes on 27 April 2023 at DUK Professional Conference

Entry deadline: 7 July 2023

To receive launch information as soon as available, contact: Debbie Tuesley, dtuesley@pmlive.com

ABCD audits update 2023

Dr Bob Ryder

ABCD Meeting, Royal College of Physicians, Edinburgh

September 6, 2023

Association of British Clinical Diabetologists

Disclosures

- Dr Bob Ryder has received speaker fees, and/or consultancy fees and/or educational sponsorships from Abbott, Astra Zeneca, Besins, BioQuest, GI Dynamics and Novo Nordisk

Association of British Clinical Diabetologists

Dr Bob Ryder
ABCD Clinical Lead

Dr Piya Sen Gupta
ABCD Research Fellow

Dr Ken Thong
ABCD Research Fellow

Dr Chris Walton
ABCD Chairman 20011-2014

ABCD Nationwide Exenatide and Liraglutide Audits

ABCD
Association of British Clinical Diabetologists

Dr Piya Sen Gupta
ABCD Research Fellow

Dr Ken Thong
ABCD Research Fellow

Dr Mahi Yadagiri
ABCD Research Fellow

Dr Harshal Deshmukh
ABCD Research Fellow

Dr Tom Crabtree
ABCD Research Fellow

ABCD Nationwide and Worldwide Audits

ABCD
Association of British Clinical Diabetologists

15:00 - 15:30

Rising stars

Location: Conference Centre

15.00 - Reflections of an ABCD Research Fellow, Dr Thomas Crabtree

15.15 - My journey with the Association of British Clinical Diabetologists (ABCD) FSL audit, Dr Harshal Deshmukh

Dr. Harshal Deshmukh, University of Hull UK

Dr. Tom Crabtree, University Hospitals of Derby and Burton NHS Trust

Dr Harshal Deshmukh
ABCD Research Fellow

Dr Tom Crabtree
ABCD Research Fellow

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Dr. Harshal Deshmukh, University of Hull UK

Dr. Tom Crabtree, University Hospitals of Derby and Burton NHS Trust

- Between them Drs Crabtree and Deshmukh will cover ABCD audits of new diabetes technologies

Dr Harshal Deshmukh
ABCD Research Fellow

Dr Tom Crabtree
ABCD Research Fellow

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Dr. Harshal Deshmukh, University of Hull UK

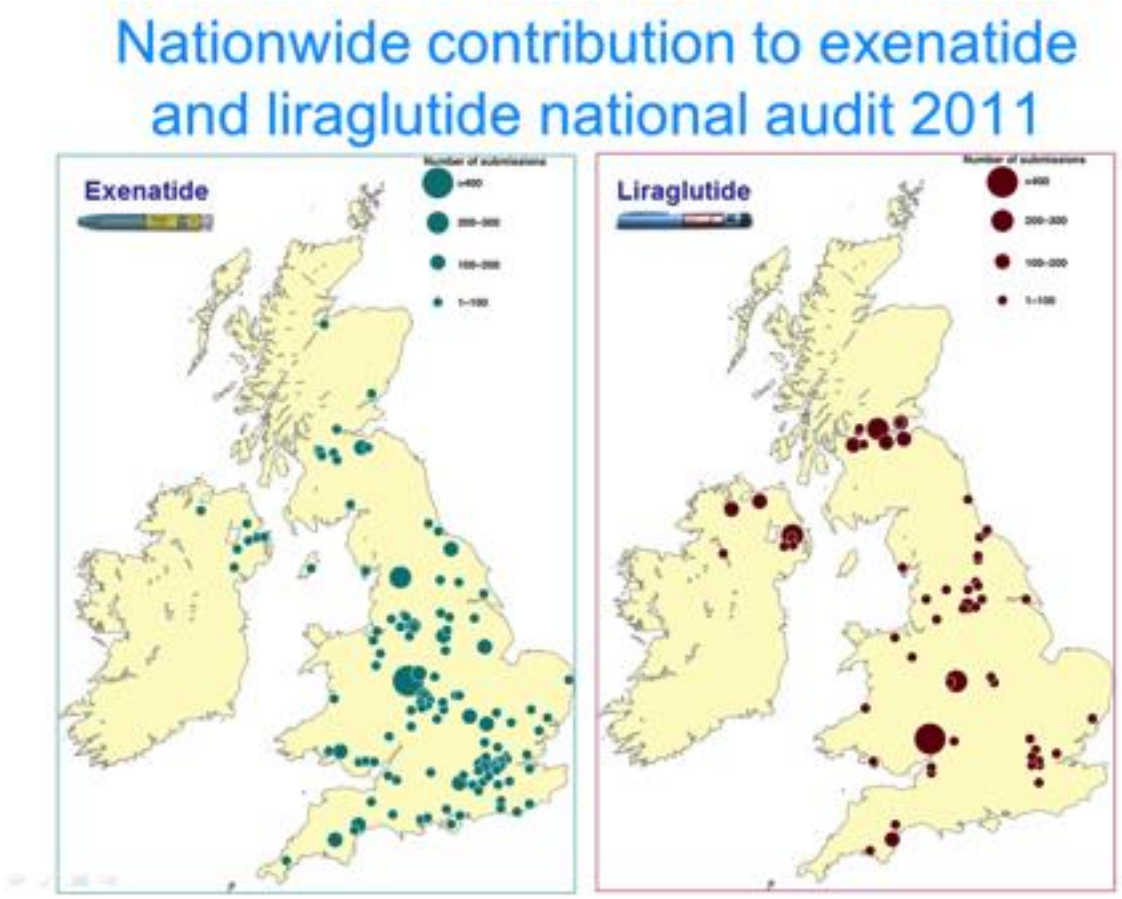
Dr. Tom Crabtree, University Hospitals of Derby and Burton NHS Trust

- Between them Drs Crabtree and Deshmukh will cover ABCD audits of new diabetes technologies
- I will cover everything else:
  - ABCD audits of new diabetes therapies
  - ABCD COVID19 & Diabetes Audit
  - ABCD EndoBarrier worldwide registry

Dr Harshal Deshmukh
ABCD Research Fellow

Dr Tom Crabtree
ABCD Research Fellow

ABCD nationwide exenatide and liraglutide audits



- Real-life data
  - >13000 patients from
  - >150 centres
  - >500 contributors
- There have been
  - 14 published papers
  - 24 abstracts
  - 13 oral presentations

https://abcd.care/abcd-nationwide-exenatide-audit-publications
https://abcd.care/abcd-nationwide-liraglutide-audit-publications

ABCD
Association of British Clinical Diabetologists

Combined trials vs real world

	Clinical trials combined	Real clinical use in UK (ABCD audit)
	Baseline HbA_{1c} (%)	
Exenatide	8.37	9.47
Liraglutide	8.5	9.40
	Baseline BMI (kg/m^2)	
Exenatide	32.72	39.8
Liraglutide	31	39.0

- Real world patients more poorly controlled and heavier than in the clinical trials
- Nevertheless, the agents have proven to be very effective

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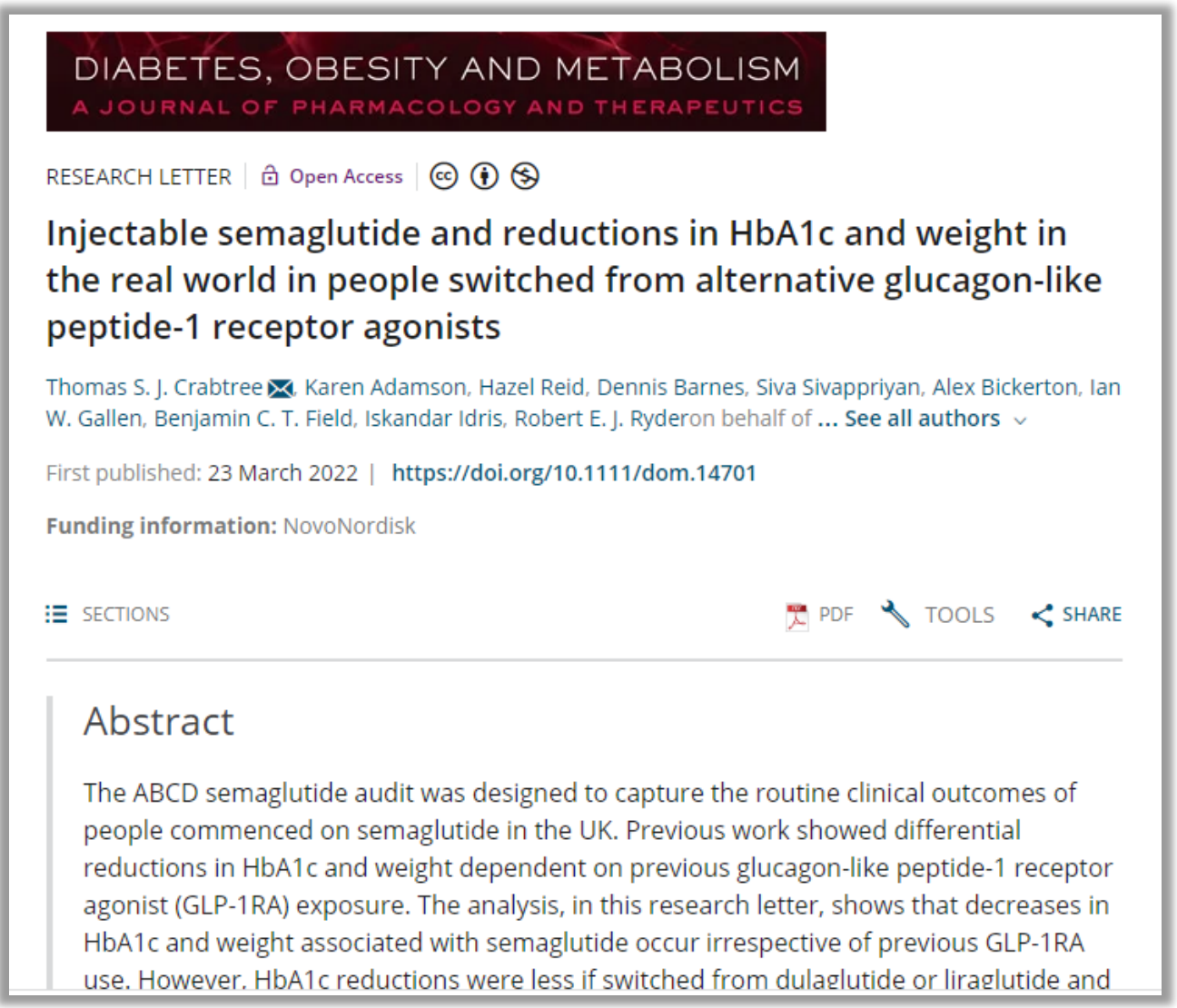
- Real world patients more poorly controlled and heavier than in the clinical trials
- Nevertheless, the agents have proven to be very effective
- We have found this phenomenon in ALL our audits of:
  - GLP-1 receptor agonists
  - SGLT2 inhibitors

ABCD
Association of British Clinical Diabetologists

ABCD nationwide semaglutide audit



DIABETES, OBESITY AND METABOLISM
A JOURNAL OF PHARMACOLOGY AND THERAPEUTICS

RESEARCH LETTER | Open Access

Injectable semaglutide and reductions in HbA1c and weight in the real world in people switched from alternative glucagon-like peptide-1 receptor agonists

Thomas S. J. Crabtree, Karen Adamson, Hazel Reid, Dennis Barnes, Siva Sivappriyan, Alex Bickerton, Ian W. Gallen, Benjamin C. T. Field, Iskandar Idris, Robert E. J. Ryder on behalf of ... See all authors

First published: 23 March 2022 | https://doi.org/10.1111/dom.14701

Funding information: NovoNordisk

SECTIONS PDF TOOLS SHARE

Abstract

The ABCD semaglutide audit was designed to capture the routine clinical outcomes of people commenced on semaglutide in the UK. Previous work showed differential reductions in HbA1c and weight dependent on previous glucagon-like peptide-1 receptor agonist (GLP-1RA) exposure. The analysis, in this research letter, shows that decreases in HbA1c and weight associated with semaglutide occur irrespective of previous GLP-1RA use. However, HbA1c reductions were less if switched from dulaglutide or liraglutide and

- Patients heavier and more poorly controlled than in the clinical trials
- Considerable reductions in weight and HbA1c
- Those switched to semaglutide from other GLP1-RAs demonstrated significant additional reductions in HbA1c and weight after making the switch

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ABCD nationwide semaglutide audit

HbA1c and weight changes with semaglutide at 6- and 12-months post commencement: updated results from the ABCD semaglutide audit

- HbA1c reductions associated with semaglutide observed in the first 6-months persist at one year
- Weight continues to be lost beyond the initial 6-month period

Association of British Clinical Diabetologists

Exenatide audit: off licence use with insulin

original article

Diabetes, Obesity and Metabolism 13: 703–710, 2011.

Safety, efficacy and tolerability of exenatide in combination with insulin in the Association of British Clinical Diabetologists nationwide exenatide audit*

ORIGINAL ARTICLE

K. Y. Thong[1], B. Jose[1], N. Sukumar[1], M. L. Cull[1], A. P. Mills[1], T. Sathyapalan[2], W. Shafiq[2], A. S. Rigby[2], C. Walton[2] & R. E. J. Ryder[1] on behalf of the ABCD nationwide exenatide audit contributors†

[1]Department of Diabetes, City Hospital, Birmingham, UK
[2]Department of Diabetes, Hull Royal Infirmary, Hull, UK

Aim: To assess the extent, safety, efficacy and tolerability of reported off-licence exenatide use through a nationwide audit.
Methods: The Association of British Clinical Diabetologists hosted a password-protected, online collection of anonymized data of exenatide use in real clinical practice. Three hundred and fifteen contributors from 126 centres across UK provided data on 6717 patients. HbA1c and weight changes, exenatide discontinuation, adverse events and treatment satisfaction were compared between non-insulin and insulin-treated patients.
Results: Four thousand eight hundred and fifty-seven patients had baseline and follow-up treatment status with mean (±s.d.) baseline HbA1c 9.45 ± 1.69% and BMI 40.0 ± 8.2 kg/m^2. Of the 4857 patients, 1921 (39.6%) used exenatide with insulin. Comparing patients who continued insulin with exenatide with non-insulin-treated patients, mean (±s.e.) latest HbA1c and weight reduction (median 26 weeks) were 0.51 ± 0.06 versus 0.94 ± 0.04% ($p < 0.001$) and 5.8 ± 0.2 versus 5.5 ± 0.1 kg ($p = 0.278$). Insulin-treated patients had higher rates of exenatide discontinuation (31.0 vs. 13.9%, $p < 0.001$), hypoglycaemia (8.9 vs. 6.1%, $p < 0.001$), gastrointestinal side effects (28.4 vs. 25.0%, $p = 0.008$) and treatment dissatisfaction (20.8 vs. 5.7%, $p < 0.001$). However, 34.2% of the patients continuing insulin still achieved HbA1c reduction ≥1%. There was significant insulin discontinuation, dose reduction and greater sulphonylurea discontinuation among insulin-treated patients.
Conclusions: Addition of exenatide to obese, insulin-treated patients can improve glycaemia and weight. Adverse events were statistically but probably not clinically significantly higher, but combination treatment was less well tolerated. Overall, exenatide was less effective in lowering HbA1c among insulin-treated patients, although significant number of insulin-treated patients still achieved significant HbA1c, weight and insulin reductions. Further research into identifying obese, insulin-treated patients who will tolerate and benefit from exenatide treatment is urgently needed.
Keywords: exenatide, GLP-1 analogue, incretin therapy, insulin therapy, type 2 diabetes

Date submitted 29 December 2010; date of first decision 7 February 2011; date of final acceptance 9 March 2011

- Off licence exenatide with insulin safe and effective in real clinical practice
- Reduction in insulin dose frequently occurred
- Weight fell
- 1 in 6 patients came off insulin

Thong et al. Diabetes, Obesity and Metabolism 2011; 13(8): 703-710

ABCD
Association of British Clinical Diabetologists

Exenatide audit: important safety issue uncovered

DIABETES RESEARCH AND CLINICAL PRACTICE 93 (2011) e87–e91

Contents lists available at ScienceDirect

Diabetes Research and Clinical Practice

journal homepage: www.elsevier.com/locate/diabres

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International Diabetes Federation

Brief report

Response at 3 months to insulin dose decisions made at exenatide initiation in the Association of British Clinical Diabetologists (ABCD) nationwide exenatide audit

K.Y. Thong [a,1,*], B. Jose [a,1], A.D. Blann [a,1], M.L. Cull [a,1], A.P. Mills [a,1], T. Sathyapalan [b,1], C. Walton [b,1], R.E.J. Ryder [a,1]

[a] City Hospital, Birmingham, United Kingdom
[b] Hull Royal Infirmary, Hull, United Kingdom

ARTICLE INFO

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Keywords:
Exenatide
GLP-1 agonist
Insulin treatment
Obesity
Type 2 diabetes

ABSTRACT

It is uncertain what should be done with insulin dose if starting exenatide. In the ABCD nationwide exenatide audit, many patients with type 2 diabetes had worsened glycaemia when insulin was stopped. If starting exenatide, insulin should not be stopped but weaned off only if there is significant glycaemic response.

- Some clinicians attempted to stop insulin when starting exenatide in order to stay within guidelines
- This led to harm in some patients
- Seven cases of diabetic ketoacidosis in patients who stopped insulin at the time of exenatide initiation
- Analysis of audit data allowed us to recommend that when starting a GLP1-RA in an insulin-treated patient not to stop the insulin but rather to tail the insulin off during treatment if response to treatment allowed

Thong et al. Diabetes Res Clin Pract. 2011; 93(2): e87-e91

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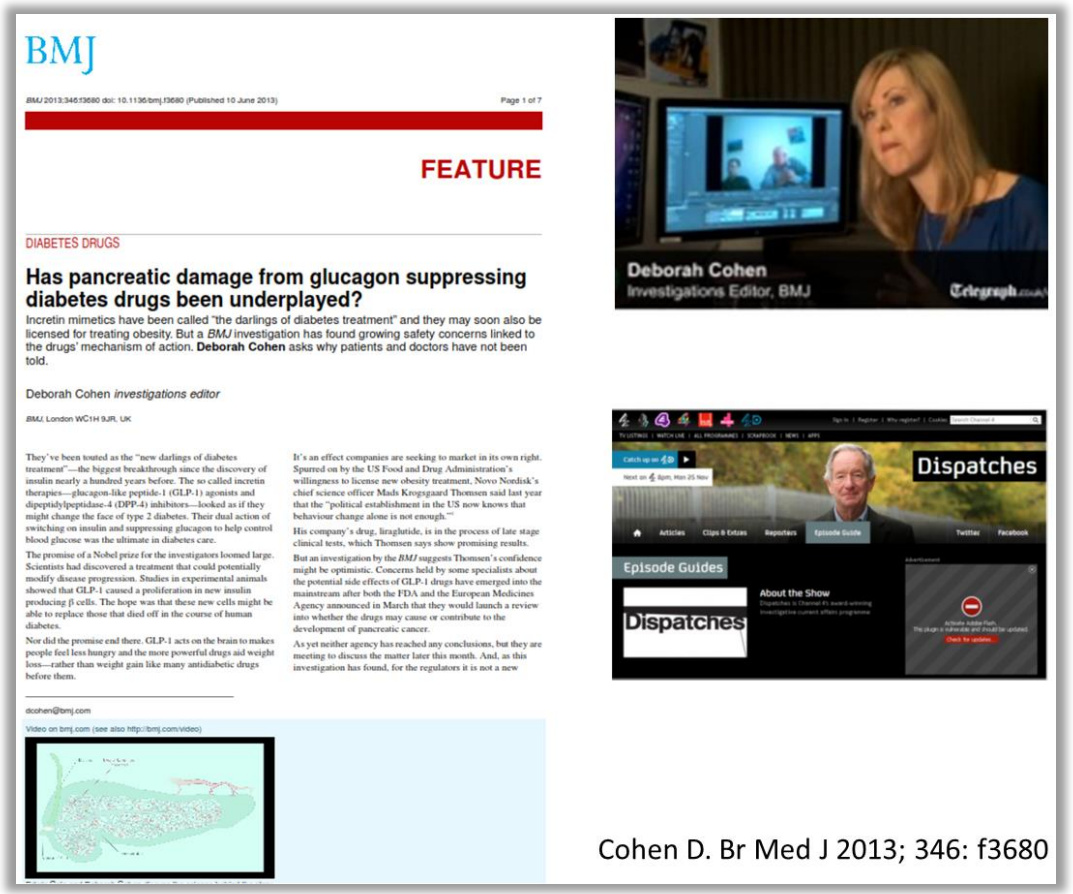
ABCD audit data allowed us to re-assure about pancreatitis



BMJ

BMJ 2013;346:f3680 doi: 10.1136/bmj.f3680 (Published 10 June 2013) Page 1 of 7

FEATURE

DIABETES DRUGS

Has pancreatic damage from glucagon suppressing diabetes drugs been underplayed?

Incretin mimetics have been called "the darlings of diabetes treatment" and they may soon also be licensed for treating obesity. But a *BMJ* investigation has found growing safety concerns linked to the drugs' mechanism of action. **Deborah Cohen** asks why patients and doctors have not been told.

Deborah Cohen *investigations editor*

BMJ, London WC1H 9JR, UK

They've been touted as the "new darlings of diabetes treatment"—the biggest breakthrough since the discovery of insulin nearly a hundred years before. The so called incretin therapies—glucagon-like peptide-1 (GLP-1) agonists and dipeptidylpeptidase-4 (DPP-4) inhibitors—looked as if they might change the face of type 2 diabetes. Their dual action of switching on insulin and suppressing glucagon to help control blood glucose was the ultimate in diabetes care.

The promise of a Nobel prize for the investigators loomed large. Scientists had discovered a treatment that could potentially modify disease progression. Studies in experimental animals showed that GLP-1 caused a proliferation in new insulin producing β cells. The hope was that these new cells might be able to replace those that died off in the course of human diabetes.

Nor did the promise end there. GLP-1 acts on the brain to makes people feel less hungry and the more powerful drugs aid weight loss—rather than weight gain like many antidiabetic drugs before them.

It's an effect companies are seeking to market in its own right. Spurred on by the US Food and Drug Administration's willingness to license new obesity treatment, Novo Nordisk's chief science officer Mads Krogsgaard Thomsen said last year that the "political establishment in the US now knows that behaviour change alone is not enough."[1]

His company's drug, liraglutide, is in the process of late stage clinical tests, which Thomsen says show promising results.

But an investigation by the *BMJ* suggests Thomsen's confidence might be optimistic. Concerns held by some specialists about the potential side effects of GLP-1 drugs have emerged into the mainstream after both the FDA and the European Medicines Agency announced in March that they would launch a review into whether the drugs may cause or contribute to the development of pancreatic cancer.

As yet neither agency has reached any conclusions, but they are meeting to discuss the matter later this month. And, as this investigation has found, for the regulators it is not a new

dcohen@bmj.com

Video on bmj.com (see also http://bmj.com/video)

Cohen D. Br Med J 2013; 346: f3680

- Alarm raised (BMJ and Channel 4 Dispatches TV programme) in 2013 that incretin therapies might cause pancreatic damage
- We have been able to contribute by publishing data suggesting that in the ABCD audits there is no evidence of such a side effect:

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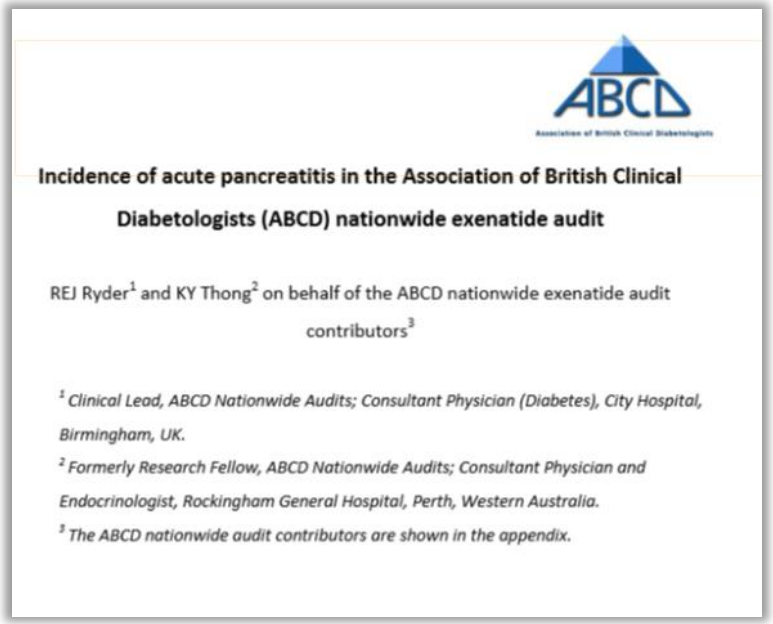
ABCD audit data allowed us to re-assure about pancreatitis



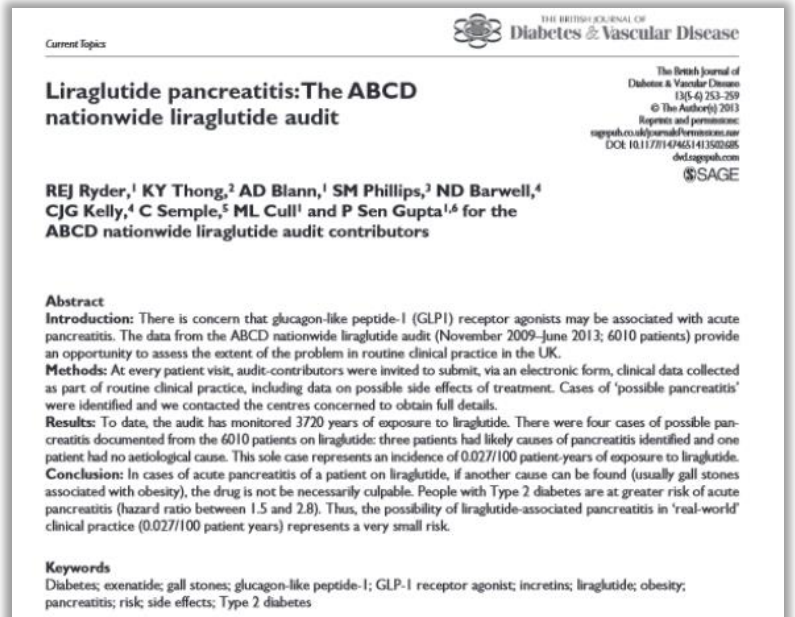
Incidence of acute pancreatitis in the Association of British Clinical Diabetologists (ABCD) nationwide exenatide audit

REJ Ryder[1] and KY Thong[2] on behalf of the ABCD nationwide exenatide audit contributors[3]

[1] Clinical Lead, ABCD Nationwide Audits; Consultant Physician (Diabetes), City Hospital, Birmingham, UK.

[2] Formerly Research Fellow, ABCD Nationwide Audits; Consultant Physician and Endocrinologist, Rockingham General Hospital, Perth, Western Australia.

[3] The ABCD nationwide audit contributors are shown in the appendix.



Current Topics

The British Journal of Diabetes & Vascular Disease

Liraglutide pancreatitis: The ABCD nationwide liraglutide audit

The British Journal of Diabetes & Vascular Disease
13(5-6) 253-259
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DOI: 10.1177/1474651413502685
dvd.sagepub.com
SAGE

REJ Ryder,[1] KY Thong,[2] AD Blann,[1] SM Phillips,[3] ND Barwell,[4] CJG Kelly,[4] C Semple,[5] ML Cull[1] and P Sen Gupta[1,6] for the ABCD nationwide liraglutide audit contributors

Abstract

Introduction: There is concern that glucagon-like peptide-1 (GLP1) receptor agonists may be associated with acute pancreatitis. The data from the ABCD nationwide liraglutide audit (November 2009–June 2013; 6010 patients) provide an opportunity to assess the extent of the problem in routine clinical practice in the UK.

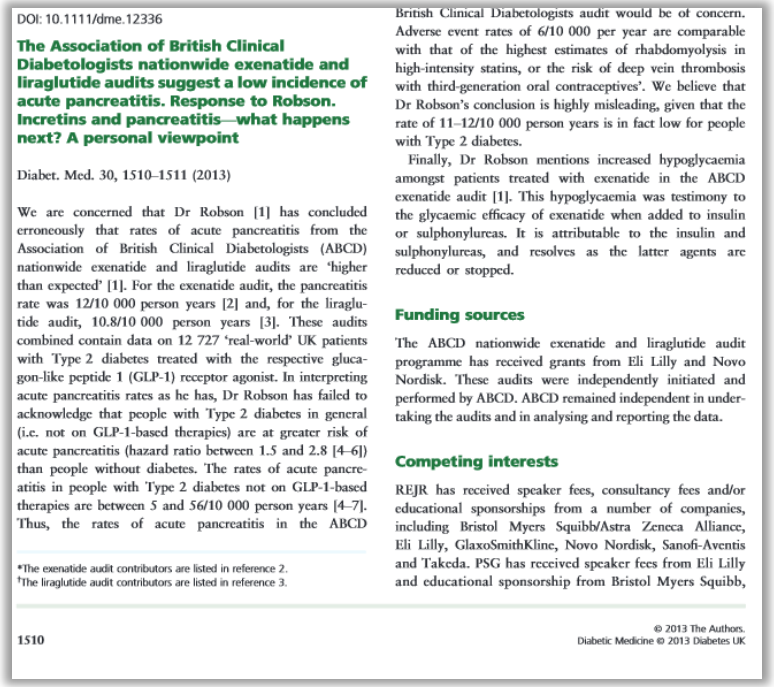
Methods: At every patient visit, audit-contributors were invited to submit, via an electronic form, clinical data collected as part of routine clinical practice, including data on possible side effects of treatment. Cases of 'possible pancreatitis' were identified and we contacted the centres concerned to obtain full details.

Results: To date, the audit has monitored 3720 years of exposure to liraglutide. There were four cases of possible pancreatitis documented from the 6010 patients on liraglutide: three patients had likely causes of pancreatitis identified and one patient had no aetiological cause. This sole case represents an incidence of 0.027/100 patient-years of exposure to liraglutide.

Conclusion: In cases of acute pancreatitis of a patient on liraglutide, if another cause can be found (usually gall stones associated with obesity), the drug is not be necessarily culpable. People with Type 2 diabetes are at greater risk of acute pancreatitis (hazard ratio between 1.5 and 2.8). Thus, the possibility of liraglutide-associated pancreatitis in 'real-world' clinical practice (0.027/100 patient years) represents a very small risk.

Keywords

Diabetes; exenatide; gall stones; glucagon-like peptide-1; GLP-1 receptor agonist; incretins; liraglutide; obesity; pancreatitis; risk; side effects; Type 2 diabetes



DOI: 10.1111/dme.12336

The Association of British Clinical Diabetologists nationwide exenatide and liraglutide audits suggest a low incidence of acute pancreatitis. Response to Robson. Incretins and pancreatitis—what happens next? A personal viewpoint

Diabet. Med. 30, 1510–1511 (2013)

We are concerned that Dr Robson [1] has concluded erroneously that rates of acute pancreatitis from the Association of British Clinical Diabetologists (ABCD) nationwide exenatide and liraglutide audits are 'higher than expected' [1]. For the exenatide audit, the pancreatitis rate was 12/10 000 person years [2] and, for the liraglutide audit, 10.8/10 000 person years [3]. These audits combined contain data on 12 727 'real-world' UK patients with Type 2 diabetes treated with the respective glucagon-like peptide 1 (GLP-1) receptor agonist. In interpreting acute pancreatitis rates as he has, Dr Robson has failed to acknowledge that people with Type 2 diabetes in general (i.e. not on GLP-1-based therapies) are at greater risk of acute pancreatitis (hazard ratio between 1.5 and 2.8 [4–6]) than people without diabetes. The rates of acute pancreatitis in people with Type 2 diabetes not on GLP-1-based therapies are between 5 and 56/10 000 person years [4–7]. Thus, the rates of acute pancreatitis in the ABCD British Clinical Diabetologists audit would be of concern. Adverse event rates of 6/10 000 per year are comparable with that of the highest estimates of rhabdomyolysis in high-intensity statins, or the risk of deep vein thrombosis with third-generation oral contraceptives'. We believe that Dr Robson's conclusion is highly misleading, given that the rate of 11–12/10 000 person years is in fact low for people with Type 2 diabetes.

Finally, Dr Robson mentions increased hypoglycaemia amongst patients treated with exenatide in the ABCD exenatide audit [1]. This hypoglycaemia was testimony to the glycaemic efficacy of exenatide when added to insulin or sulphonylureas. It is attributable to the insulin and sulphonylureas, and resolves as the latter agents are reduced or stopped.

*The exenatide audit contributors are listed in reference 2.
†The liraglutide audit contributors are listed in reference 3.

Funding sources

The ABCD nationwide exenatide and liraglutide audit programme has received grants from Eli Lilly and Novo Nordisk. These audits were independently initiated and performed by ABCD. ABCD remained independent in undertaking the audits and in analysing and reporting the data.

Competing interests

REJR has received speaker fees, consultancy fees and/or educational sponsorships from a number of companies, including Bristol Myers Squibb/Astra Zeneca Alliance, Eli Lilly, GlaxoSmithKline, Novo Nordisk, Sanofi-Aventis and Takeda. PSG has received speaker fees from Eli Lilly and educational sponsorship from Bristol Myers Squibb,

- Rates of acute pancreatitis in the ABCD exenatide and liraglutide audits were at the low end of the rates expected for people with type 2 diabetes in general
- 75% of the cases of acute pancreatitis in the ABCD exenatide and liraglutide audits had other causes for acute pancreatitis, in particular gall bladder disease

Association of British Clinical Diabetologists

Diabetes and NAFLD – impact of GLP-1 RA on ALT

ORIGINAL RESEARCH

Reductions in alanine aminotransferase levels with liraglutide treatment are greatest in those with raised baseline levels and are independent of weight loss: real-world outcome data from the ABCD Nationwide Liraglutide Audit

THOMAS SJ CRABTREE,[1] SUSANNAH ROWLES,[2] STEPHANIE TARPEY,[2] ADELE KENNEDY,[3,4] JOHN CHALMERS,[5] RAHUL NAYAR,[6] AMANDA LEE,[6] KEN DARZY,[7] PETER WINOCOUR,[7] JOHN LINDSAY,[8] ISKANDAR IDRIS,[9] KEN Y THONG,[10] PIYA SEN GUPTA,[11] AMAR PUTTANNA,[12] PRANAV KUMAR,[13] ROBERT EJ RYDER,[14] ON BEHALF OF ABCD NATIONWIDE AUDIT CONTRIBUTORS

Abstract

People with type 2 diabetes mellitus experience an increased prevalence of non-alcoholic fatty liver disease (NAFLD) compared with the general population and often with worse outcomes. As part of the ABCD Liraglutide Nationwide Audit Programme, we obtained and analysed data from 2009 to excluding those with insufficient or incomplete data, we analysed the results from 1,759 patients treated in the real-world clinical setting. Our results demonstrated an overall significant decrease in median ALT (–1 U/L, 95% CI –1 to –2, p<0.001) compared with baseline, which was more pronounced in patients with elevated ALT based on gender-

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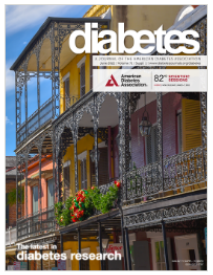

Previous Article | Next Article

P: CLINICAL THERAPEUTICS / NEW TECHNOLOGY—INCRETIN-BASED THERAPIES | JUNE 01 2022

756-P: The Effect of Semaglutide on Alanine Aminotransferase (ALT) Levels: Results from the Association of British Clinical Diabetologists (ABCD) Audit FREE

THOMAS S.J. CRABTREE; DEVESH K. SENNIK; ALEX BICKERTON; DENNIS BARNES; SIVA SIVAPPRIYAN; KAREN ADAMSON; SUZANNE M. PHILLIPS; ALISON EVANS; NIELS LARSEN; AVINASH PANESAR; MELISSA L. CULL; IAN W. GALLEN; ISKANDAR R. IDRIS; ROBERT E. RYDER

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Diabetes 2022;71(Supplement_1):756-P
https://doi.org/10.2337/db22-756-P

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Obesity and type 2 diabetes are important drivers for the development of nonalcoholic fatty liver disease (NAFLD) . Glucagon-like peptide-1 receptor agonists (GLP1RAs) are efficacious for these conditions, but their potential as treatments for NAFLD remains unclear. As serum ALT concentration is routinely measured in clinical care, we evaluated the impact of the GLP1RA, semaglutide, on ALT in those at risk of NAFLD.

Methods: Data submitted to the ABCD semaglutide audit (launched in 2019) were analysed.

- Among patients with raised ALT, liraglutide and semaglutide associated with ALT reduction

ABCD
Association of British Clinical Diabetologists

GLP1-RA – predicting treatment response

LEARNING FROM PRACTICE

Insulin treatment and longer diabetes duration both predict poorer glycaemic response to liraglutide treatment in type 2 diabetes: the Association of British Clinical Diabetologists Nationwide Liraglutide Audit

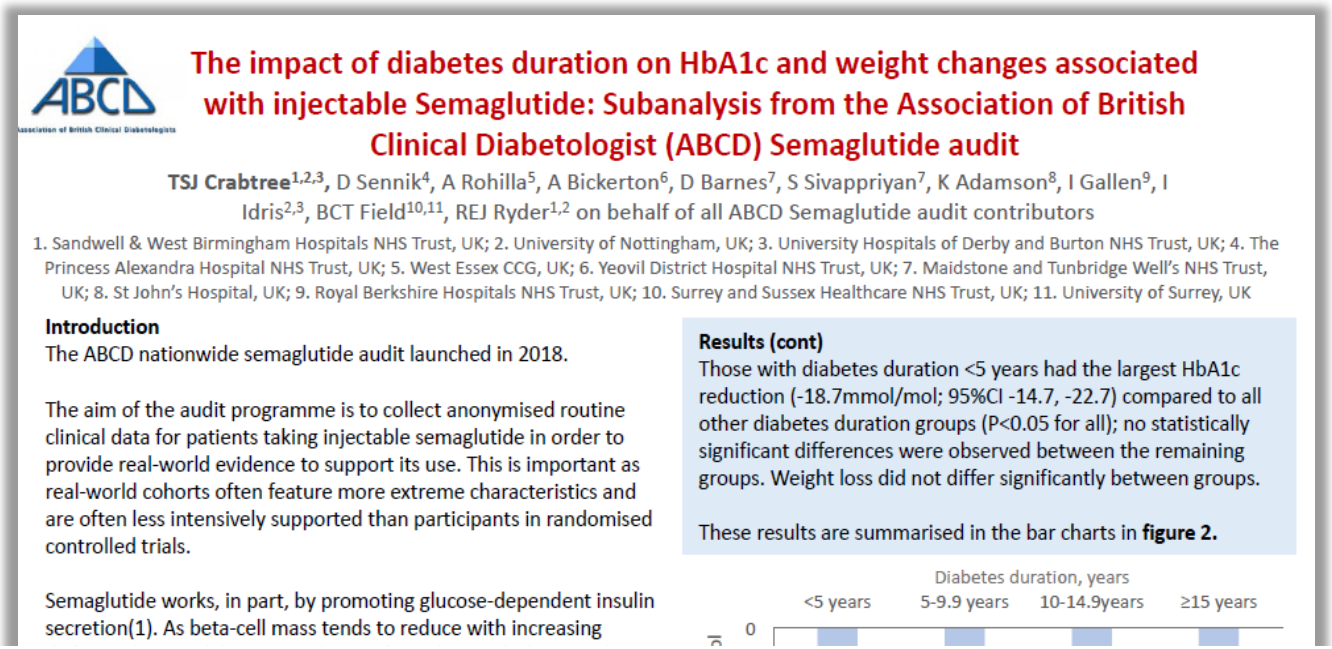
KEN Y THONG,[1] BARBARA M MCGOWAN,[2] THEIN HTAY,[3] ANDREW PERNET,[4] CHRIS KELLY,[5] CHINNADORAI RAJESWARAN,[6] JILL HOWELL,[7] CATRIONA DUNCAN,[8] BERIT INKSTER,[9] LINDA BUCHANAN,[10] SAIFUL KASSIM,[11] RAHUL NAYER,[12] NICHOLAS D BARWELL,[10] CHRISTOPHER WALTON,[13] ROBERT EJ RYDER,[14] ABCD NATIONWIDE LIRAGLUTIDE AUDIT CONTRIBUTORS[15]

Abstract

Background: **Liraglutide may be less effective in patients with more advanced type 2 diabetes. This study from the**

in HbA_{1c} were compared across groups after adjusting for baseline HbA_{1c}.

Results: **After exclusions to standardise comparisons, 937**



The impact of diabetes duration on HbA1c and weight changes associated with injectable Semaglutide: Subanalysis from the Association of British Clinical Diabetologist (ABCD) Semaglutide audit

TSJ Crabtree[1,2,3], D Sennik[4], A Rohilla[5], A Bickerton[6], D Barnes[7], S Sivappriyan[7], K Adamson[8], I Gallen[9], I Idris[2,3], BCT Field[10,11], REJ Ryder[1,2] on behalf of all ABCD Semaglutide audit contributors

1. Sandwell & West Birmingham Hospitals NHS Trust, UK; 2. University of Nottingham, UK; 3. University Hospitals of Derby and Burton NHS Trust, UK; 4. The Princess Alexandra Hospital NHS Trust, UK; 5. West Essex CCG, UK; 6. Yeovil District Hospital NHS Trust, UK; 7. Maidstone and Tunbridge Well's NHS Trust, UK; 8. St John's Hospital, UK; 9. Royal Berkshire Hospitals NHS Trust, UK; 10. Surrey and Sussex Healthcare NHS Trust, UK; 11. University of Surrey, UK

Introduction

The ABCD nationwide semaglutide audit launched in 2018.

The aim of the audit programme is to collect anonymised routine clinical data for patients taking injectable semaglutide in order to provide real-world evidence to support its use. This is important as real-world cohorts often feature more extreme characteristics and are often less intensively supported than participants in randomised controlled trials.

Semaglutide works, in part, by promoting glucose-dependent insulin secretion(1). As beta-cell mass tends to reduce with increasing

Results (cont)

Those with diabetes duration <5 years had the largest HbA1c reduction (-18.7mmol/mol; 95%CI -14.7, -22.7) compared to all other diabetes duration groups (P<0.05 for all); no statistically significant differences were observed between the remaining groups. Weight loss did not differ significantly between groups.

These results are summarised in the bar charts in **figure 2.**

- Liraglutide and semaglutide associated associated with greater HbA1c reduction in those with shorter duration of diabetes

Association of British Clinical Diabetologists

First data from the oral semaglutide audit

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Activity: Abstract
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Glucose and weight outcomes associated with oral semaglutide in the real-world: Initial results from the Association of British Clinical Diabetologists' (ABCD) audit

Author Block: THOMAS S.J. CRABTREE, KAREN ADAMSON, SENTHILKUMAR KRISHNASAMY, MAY THIN KHINE, PARIJAT DE, RAJESH PETER, **ROBERT E. RYDER**, *Livingston, United Kingdom, WALSALL, United Kingdom, BIRMINGHAM, United Kingdom, Port Talbot, United Kingdom*

Abstract:
Semaglutide is the first glucagon like peptide-1 receptor agonist (GLP1-RA) available in an oral preparation. Weight and HbA1c outcomes with injectable semaglutide in the real-world are well established. The aim of this analysis is to assess weight and HbA1c response to oral semaglutide. **Methods** Data were extracted from the secure online ABCD audit tool. Individuals were included if baseline and follow-up weight and/or HbA1c data were available. Change in HbA1c, body mass index (BMI) and weight from baseline was assessed using a multivariate linear regression model and change in the numbers achieving an endpoint HbA1c≤7.5% [58mmol/mol] were assessed using Chi^2 tests in Stata 16. **Results** Data were available for 350 individuals with baseline mean±SD HbA1c 9.2%±1.7 [76.6mmol/mol±18.3], weight 101.8kg±21.9, BMI 34.3kg/m^2±6.9, median diabetes duration 11years (IQR 6-16) and age 59 years (IQR 51-68); 63.0% were male and 79.7% were white. Median follow-up was 0.5years (IQR 0.3-0.8). Significant reductions in HbA1c of 0.7% (95%CI 0.4, 0.9; P<0.001) [7.4mmol/mol; 95%CI 4.7, 10.0; P<0.001] were observed. Weight decreased by 3.3kg (95%CI 2.3, 4.3; P<0.001) and BMI fell by 1.1kg/m^2 (95%CI 0.6, 1.6; P<0.001). Twice as many people achieved a HbA1c≤7.5% at follow-up compared to baseline (28.6% [52/182] vs 14.3% [26/182]) - this change was statistically significant (P<0.001). **Conclusion** In the real-world, oral semaglutide is associated with statistically significant and clinically meaningful reductions in HbA1c, weight and BMI. The numbers achieving a HbA1c≤7.5% also increased. In the light of this, further data collection and analysis should be undertaken, including comparisons between oral and injectable GLP1-RAs and analysis of switches between them

Category (Complete): 12-B Clinical Therapeutics—Incretin-Based Therapies

- In the real-world, oral semaglutide is associated with statistically significant and clinically meaningful reductions in HbA1c, weight and BMI. The numbers achieving a HbA1c≤7.5% also increased.

Crabtree et al. Presented ADA 83rd Scientific Sessions, San Diego, June 2023

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SGLT2 inhibitor audits

Figure 1: Change in HbA1c at median (IQR) 4.1 (3-6.1) months after starting canagliflozin, stratified by duration of diabetes

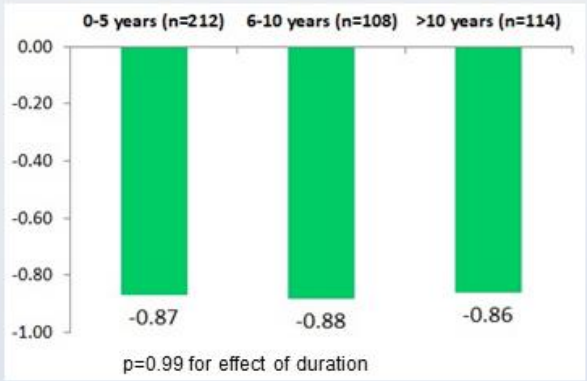
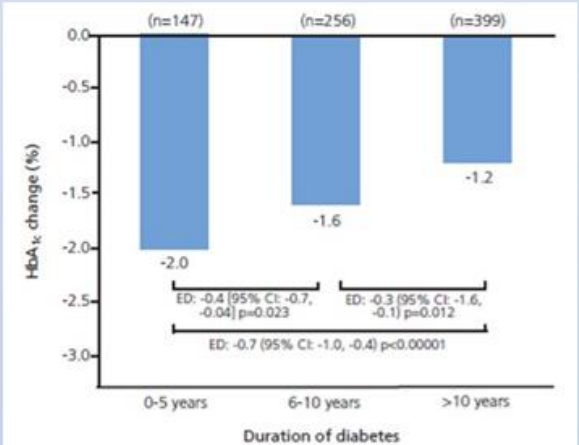


Figure 2: Change in HbA1c at 6 (3-9) months after starting liraglutide, stratified by duration of diabetes (From ABCD nationwide liraglutide audit[1] – see abstract 1038-P, ADA 2012).

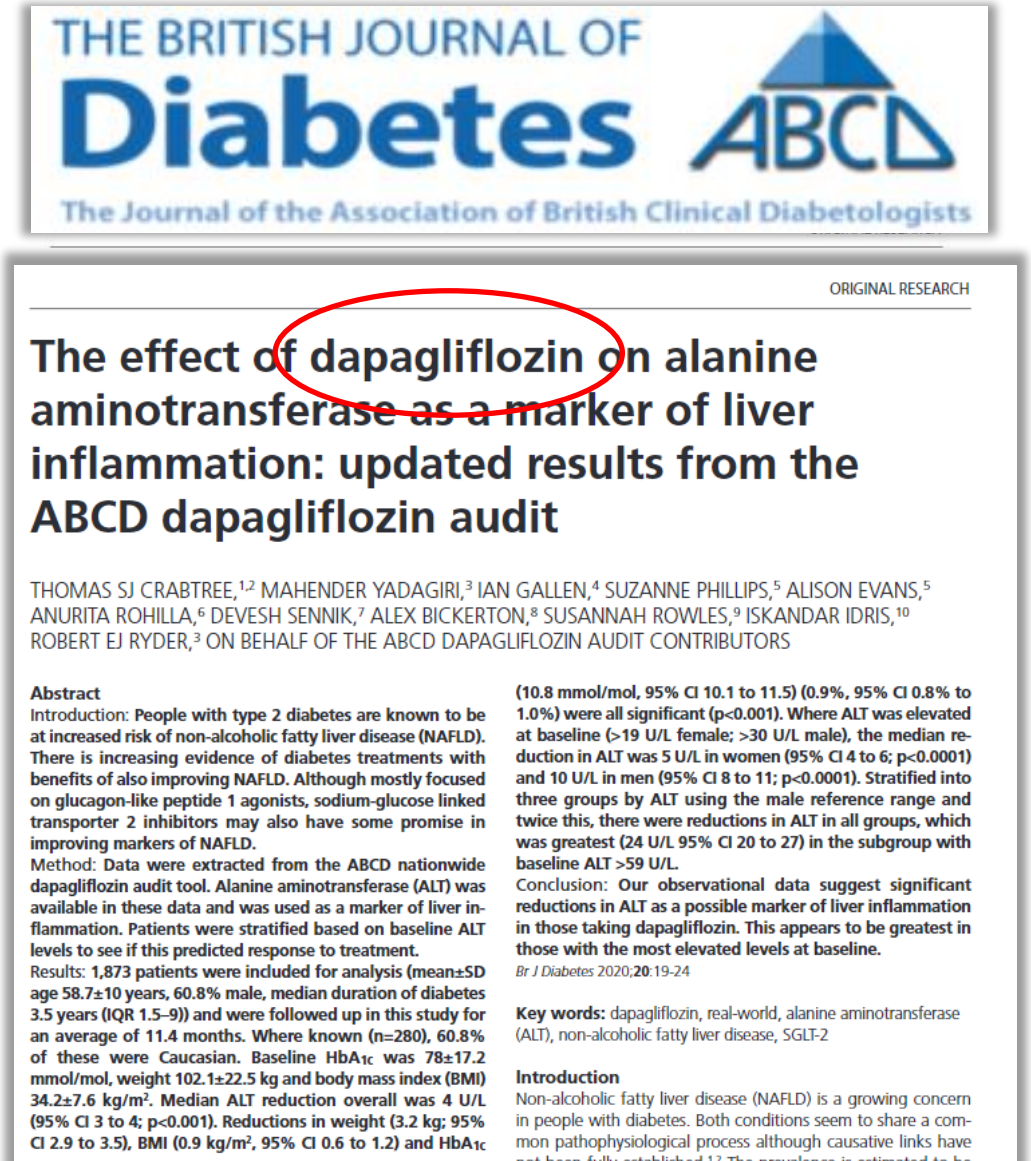


- Impact of canagliflozin on HbA1c the same regardless of diabetes duration
- Compared with findings from liraglutide audit – impact reduces with increasing duration

Presented at ADA 2019

Association of British Clinical Diabetologists

SGLT2 inhibitor audits



THE BRITISH JOURNAL OF Diabetes ABCD
The Journal of the Association of British Clinical Diabetologists

ORIGINAL RESEARCH

The effect of dapagliflozin on alanine aminotransferase as a marker of liver inflammation: updated results from the ABCD dapagliflozin audit

THOMAS SJ CRABTREE,[1,2] MAHENDER YADAGIRI,[3] IAN GALLEN,[4] SUZANNE PHILLIPS,[5] ALISON EVANS,[5] ANURITA ROHILLA,[6] DEVESH SENNIK,[7] ALEX BICKERTON,[8] SUSANNAH ROWLES,[9] ISKANDAR IDRIS,[10] ROBERT EJ RYDER,[3] ON BEHALF OF THE ABCD DAPAGLIFLOZIN AUDIT CONTRIBUTORS

Abstract

Introduction: **People with type 2 diabetes are known to be at increased risk of non-alcoholic fatty liver disease (NAFLD). There is increasing evidence of diabetes treatments with benefits of also improving NAFLD. Although mostly focused on glucagon-like peptide 1 agonists, sodium-glucose linked transporter 2 inhibitors may also have some promise in improving markers of NAFLD.**

Method: **Data were extracted from the ABCD nationwide dapagliflozin audit tool. Alanine aminotransferase (ALT) was available in these data and was used as a marker of liver inflammation. Patients were stratified based on baseline ALT levels to see if this predicted response to treatment.**

Results: **1,873 patients were included for analysis (mean±SD age 58.7±10 years, 60.8% male, median duration of diabetes 3.5 years (IQR 1.5–9)) and were followed up in this study for an average of 11.4 months. Where known (n=280), 60.8% of these were Caucasian. Baseline HbA_{1c} was 78±17.2 mmol/mol, weight 102.1±22.5 kg and body mass index (BMI) 34.2±7.6 kg/m². Median ALT reduction overall was 4 U/L (95% CI 3 to 4; p<0.001). Reductions in weight (3.2 kg; 95% CI 2.9 to 3.5), BMI (0.9 kg/m², 95% CI 0.6 to 1.2) and HbA_{1c} (10.8 mmol/mol, 95% CI 10.1 to 11.5) (0.9%, 95% CI 0.8% to 1.0%) were all significant (p<0.001). Where ALT was elevated at baseline (>19 U/L female; >30 U/L male), the median reduction in ALT was 5 U/L in women (95% CI 4 to 6; p<0.0001) and 10 U/L in men (95% CI 8 to 11; p<0.0001). Stratified into three groups by ALT using the male reference range and twice this, there were reductions in ALT in all groups, which was greatest (24 U/L 95% CI 20 to 27) in the subgroup with baseline ALT >59 U/L.**

Conclusion: **Our observational data suggest significant reductions in ALT as a possible marker of liver inflammation in those taking dapagliflozin. This appears to be greatest in those with the most elevated levels at baseline.**

Br J Diabetes 2020;**20**:19-24

Key words: dapagliflozin, real-world, alanine aminotransferase (ALT), non-alcoholic fatty liver disease, SGLT-2

Introduction

Non-alcoholic fatty liver disease (NAFLD) is a growing concern in people with diabetes. Both conditions seem to share a common pathophysiological process although causative links have

- Significant reductions in ALT as a possible marker of liver inflammation in those taking dapagliflozin.
- This appears to be greatest in those with the most elevated levels at baseline.

Crabtree et al. Br J Diabetes 2020;20:19-24

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SGLT2 inhibitor audits

Sodium-glucose linked transporter 2 inhibitors (SGLT2s) and alanine aminotransferase levels (ALT) in the Associated of British Clinical Diabetologists (ABCD) audits

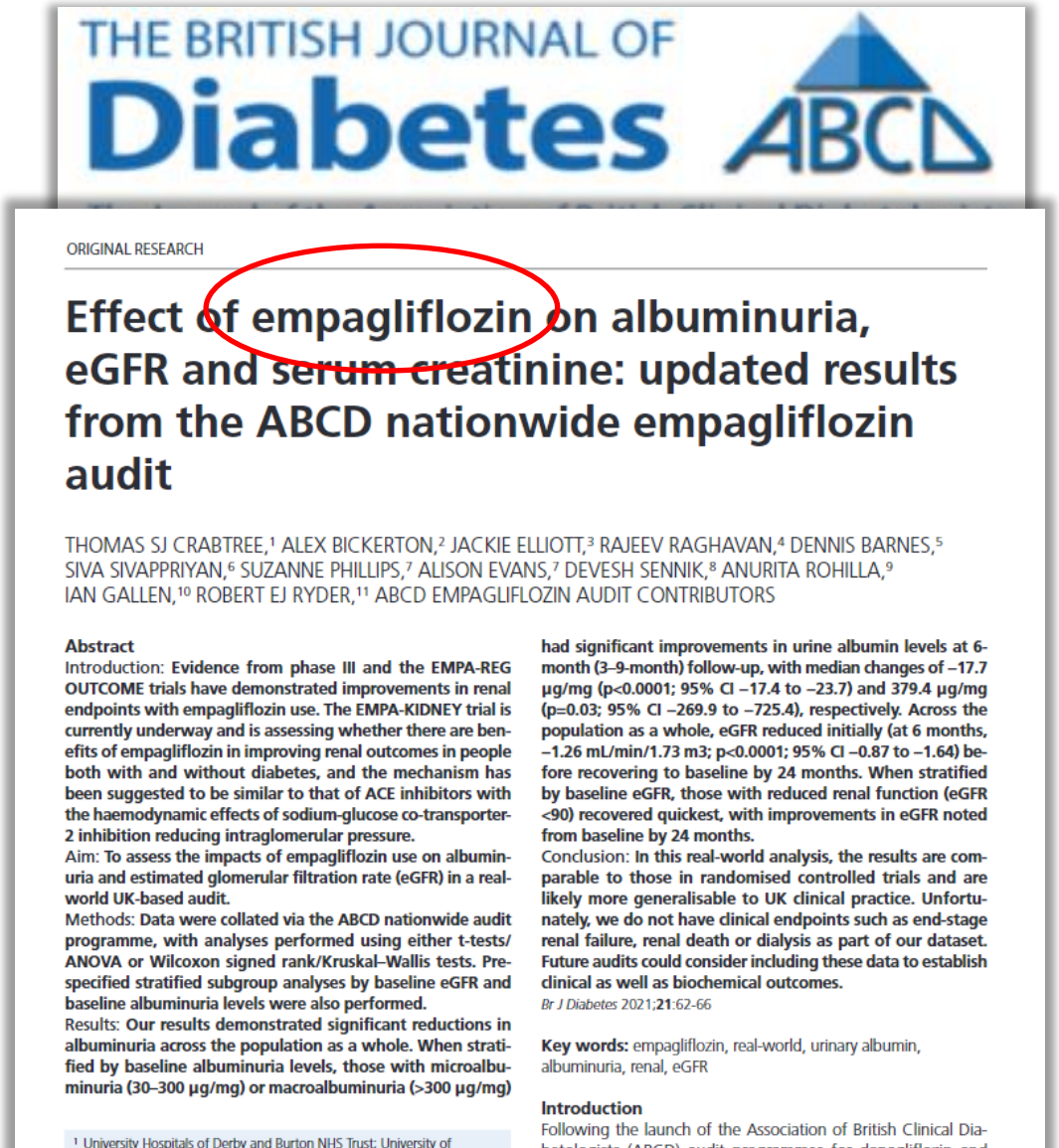
Author Block T.S.J. Crabtree[1,2], A. Gallagher[3], K. Dhatariya[4], A. Bickerton[5], J. Elliott[6], G. Rayman[7], I. Gallen[8], R.E.J. Ryder[1];
[1]Sandwell & West Birmingham Hospitals NHS Trust, Birmingham, UK, [2]University of Nottingham, Nottingham, UK,[3]University Hospitals of Leicester NHS Trust, Leicester, UK,[4]The Norfolk and Norwich University Hospitals NHS Trust, Norwich, UK,[5]Yeovil District Hospital NHS Trust, Yeovil, UK, [6]Sheffield Teaching Hospitals NHS Trust, Sheffield, UK,[7]East Suffolk & North Essex NHS Trust, Ipswich, UK,[8]Royal Berkshire NHS Foundation Trust, Reading, UK.

Abstract:
Background and aims: The ABCD SGLT2 audit programmes launched in 2014 with Dapagliflozin (D) and has since expanded to include Empagliflozin (E) and Canagliflozin (C). Results from the audit programmes has provided valuable insight into the real-world use of these drugs. Previous analyses have demonstrated reductions in ALT associated with commencement of all three drugs and may have potential implications on SGLT2 use in those with fatty liver disease. Our aim is to compare ALT changes following commencement between SGLT2 inhibitors and across the class.
Materials and methods: Data submitted to the ABCD SGLT2 audits were included providing a baseline and follow-up ALT measurement were available. Changes in ALT were also assessed within subgroups stratified by baseline ALT: group 1 ALT≤30U/L, group 2 (slight elevation) 31-60U/L; group 3 (significant elevation) >60U/L Association of ALT change

- SGLT2 inhibitors reduce Alanine Aminotransferase (ALT) across class
- Reductions greatest in those with most elevated ALT at baseline

Presented at EASD 2021

SGLT2 inhibitor audits



THE BRITISH JOURNAL OF Diabetes ABCD

ORIGINAL RESEARCH

Effect of empagliflozin on albuminuria, eGFR and serum creatinine: updated results from the ABCD nationwide empagliflozin audit

THOMAS SJ CRABTREE,[1] ALEX BICKERTON,[2] JACKIE ELLIOTT,[3] RAJEEV RAGHAVAN,[4] DENNIS BARNES,[5] SIVA SIVAPPRIYAN,[6] SUZANNE PHILLIPS,[7] ALISON EVANS,[7] DEVESH SENNIK,[8] ANURITA ROHILLA,[9] IAN GALLEN,[10] ROBERT EJ RYDER,[11] ABCD EMPAGLIFLOZIN AUDIT CONTRIBUTORS

Abstract

Introduction: **Evidence from phase III and the EMPA-REG OUTCOME trials have demonstrated improvements in renal endpoints with empagliflozin use. The EMPA-KIDNEY trial is currently underway and is assessing whether there are benefits of empagliflozin in improving renal outcomes in people both with and without diabetes, and the mechanism has been suggested to be similar to that of ACE inhibitors with the haemodynamic effects of sodium-glucose co-transporter-2 inhibition reducing intraglomerular pressure.**

Aim: **To assess the impacts of empagliflozin use on albuminuria and estimated glomerular filtration rate (eGFR) in a real-world UK-based audit.**

Methods: **Data were collated via the ABCD nationwide audit programme, with analyses performed using either t-tests/ANOVA or Wilcoxon signed rank/Kruskal–Wallis tests. Pre-specified stratified subgroup analyses by baseline eGFR and baseline albuminuria levels were also performed.**

Results: **Our results demonstrated significant reductions in albuminuria across the population as a whole. When stratified by baseline albuminuria levels, those with microalbuminuria (30–300 µg/mg) or macroalbuminuria (>300 µg/mg) had significant improvements in urine albumin levels at 6-month (3–9-month) follow-up, with median changes of −17.7 µg/mg (p<0.0001; 95% CI −17.4 to −23.7) and 379.4 µg/mg (p=0.03; 95% CI −269.9 to −725.4), respectively. Across the population as a whole, eGFR reduced initially (at 6 months, −1.26 mL/min/1.73 m3; p<0.0001; 95% CI −0.87 to −1.64) before recovering to baseline by 24 months. When stratified by baseline eGFR, those with reduced renal function (eGFR <90) recovered quickest, with improvements in eGFR noted from baseline by 24 months.**

Conclusion: **In this real-world analysis, the results are comparable to those in randomised controlled trials and are likely more generalisable to UK clinical practice. Unfortunately, we do not have clinical endpoints such as end-stage renal failure, renal death or dialysis as part of our dataset. Future audits could consider including these data to establish clinical as well as biochemical outcomes.**

Br J Diabetes 2021;**21**:62-66

Key words: empagliflozin, real-world, urinary albumin, albuminuria, renal, eGFR

Introduction

Following the launch of the Association of British Clinical Dia-

[1] University Hospitals of Derby and Burton NHS Trust; University of

- Empagliflozin led to significant reductions in albuminuria across the population as a whole
- When stratified by baseline albuminuria levels, those with microalbuminuria and macroalbuminuria both had significant improvements in urine albumin levels

Crabtree et al. Br J Diabetes 2021;21:62-66

ABCD Association of British Clinical Diabetologists

SGLT2 inhibitor audits

DIABETIC Medicine

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A41 (P230)

The effect of sodium-glucose link transporter 2 inhibitors (SGLT2i) on microalbuminuria: Cross-class analysis from the ABCD audit programme

T. S. J. Crabtree[1,2,3]; A. Gallagher[4]; I. Gallen[5]; A. Melvin[6]; J. Elliott[7]; A. Bickerton[8]; K. Dhatariya[9]; G. Rayman[10]; R. E. J. Ryder[1]

[1]*Department of Diabetes and Endocrinology, Sandwell and West Birmingham Hospitals NHS Trust, Birmingham, UK;* [2]*Department of Diabetes and Endocrinology, University Hospitals of Derby and Burton NHS Trust, Derby, UK;* [3]*School of Medicine, University of Nottingham, Nottingham, UK;* [4]*Department of Diabetes, University Hospitals of Leicester NHS Trust, Leicester, UK;* [5]*Department of Diabetes and Endocrinology, Royal Berkshire NHS FT, Reading, UK;* [6]*Department of Diabetes and Endocrinology, Bedfordshire Hospitals NHS Trust, Luton, UK;* [7]*Department of Diabetes, Sheffield Teaching Hospitals NHS Trust, Sheffield, UK;* [8]*Department of Diabetes and Endocrinology, Yeovil District Hospital NHS Trust, Yeovil, UK;* [9]*Department of Diabetes and Endocrinology, The Norfolk and Norwich University Hospitals NHS Trust, Norfolk, UK,* [10]*The Diabetes Centre and Diabetes Research Unit, East Suffolk and North East NHS FT, Suffolk, UK*

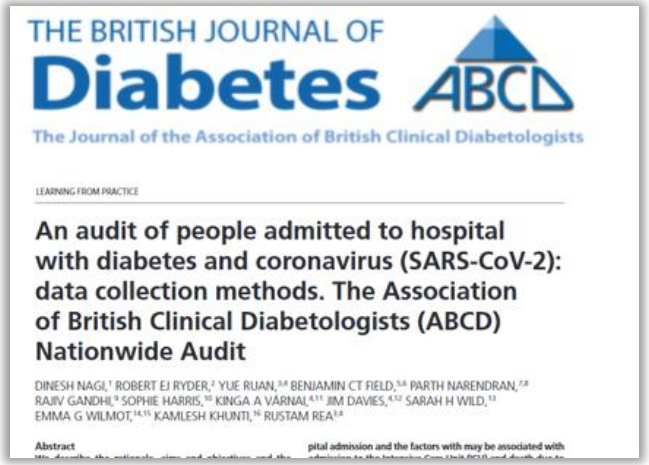
Aim: SGLT2i have recognised benefits in slowing the progression of renal disease and reducing microalbuminuria. Previous analyses from the ABCD audits demonstrated significant changes in urinary albumin creatinine ratios (uACR). This analysis aims to compare this effect across the class.

Methods: Datasets were extracted from the ABCD audit. Those with relevant data at baseline and at least one follow-up were included. Absolute and relative change uACR were assessed stratified by drug (Empa-, Dapa- and Canagliflozin) and baseline uACR (normo-, micro- and macroalbuminuria) using Wilcoxon Sign-Rank (within group) and Dunn's Test

- All SGLT2i are associated with reductions in uACR at follow-up
- These reductions greatest in those with macroalbuminuria at baseline

Presented at DUK 2022

ABCD COVID-19 and Diabetes audit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The Journal of the Association of British Clinical Diabetologists

LEARNING FROM PRACTICE

An audit of people admitted to hospital with diabetes and coronavirus (SARS-CoV-2): data collection methods. The Association of British Clinical Diabetologists (ABCD) Nationwide Audit

DINESH NAGI,[1] ROBERT EJ RYDER,[2] YUE RUAN,[3,4] BENJAMIN CT FIELD,[5,6] PARTH NARENDRAN,[7,8] RAJIV GANDHI,[9] SOPHIE HARRIS,[10] KINGA A VÁRNAI,[4,11] JIM DAVIES,[4,12] SARAH H WILD,[13] EMMA G WILMOT,[14,15] KAMLESH KHUNTI,[16] RUSTAM REA[3,4]

Abstract


Diabetes & Metabolic Syndrome: Clinical Research & Reviews 16 (2022) 102484

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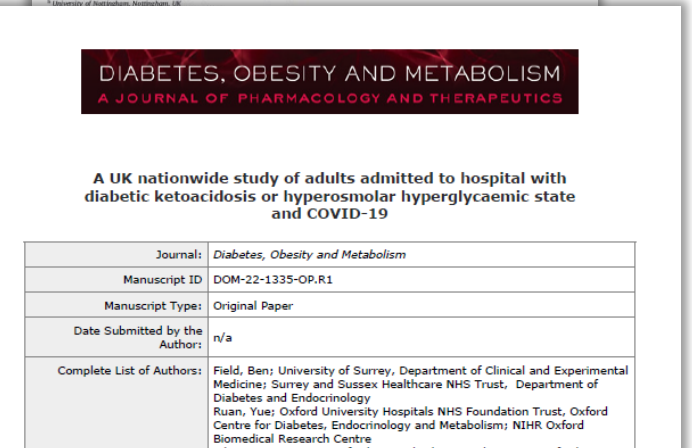
Original Article

Association of statin and/or renin-angiotensin-aldosterone system modulating therapy with mortality in adults with diabetes admitted to hospital with COVID-19: A retrospective multicentre European study

Sophie Harris [a,*,1], Yue Ruan [g,h,1], Sarah H. Wild [c,1], Matthieu Wargny [d,r], Samy Hadjadj [d], Béatrice Delasalle [f], Maëva Saignes [f], Robert EJ. Ryder [k], Benjamin C.T. Field [m,n], Parth Narendran [n,q], Francesco Zaccardi [i], Emma G. Wilmot [a,b], Bogdan Vlacho [e], Gemma Llauradó [j,l], Didac Mauricio [j,l], Dinesh Nagi [q], Dipesh Patel [s], Kinga A. Várnai [h,w], Jim Davies [h,x], Pierre Gourdy [o], Bertrand Cariou [d], Rustam Rea [g,h,1], Kamlesh Khunti [t,2], for the CORONADO, the ABCD COVID-19 diabetes national audit and HM Hospitales investigators

[a] Diabetes Department, University Hospitals of Derby and Burton NHS FT, Derby, UK

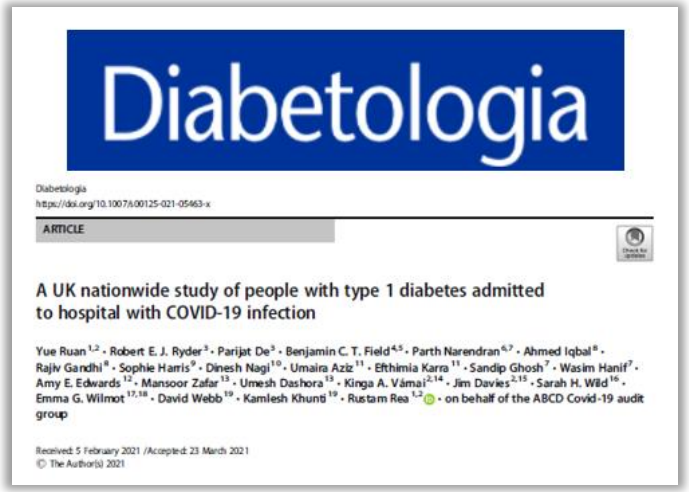
[b] University of Nottingham, Nottingham, UK


DIABETES, OBESITY AND METABOLISM

A JOURNAL OF PHARMACOLOGY AND THERAPEUTICS

A UK nationwide study of adults admitted to hospital with diabetic ketoacidosis or hyperosmolar hyperglycaemic state and COVID-19

Journal:	*Diabetes, Obesity and Metabolism*
Manuscript ID	DOM-22-1335-OP.R1
Manuscript Type:	Original Paper
Date Submitted by the Author:	n/a
Complete List of Authors:	Field, Ben; University of Surrey, Department of Clinical and Experimental Medicine; Surrey and Sussex Healthcare NHS Trust, Department of Diabetes and Endocrinology Ruan, Yue; Oxford University Hospitals NHS Foundation Trust, Oxford Centre for Diabetes, Endocrinology and Metabolism; NIHR Oxford Biomedical Research Centre


Diabetologia

https://doi.org/10.1007/s00125-021-05463-x

ARTICLE

A UK nationwide study of people with type 1 diabetes admitted to hospital with COVID-19 infection

Yue Ruan [1,2] · Robert E. J. Ryder [3] · Parijat De [3] · Benjamin C. T. Field [4,5] · Parth Narendran [6,7] · Ahmed Iqbal [8] · Rajiv Gandhi [8] · Sophie Harris [9] · Dinesh Nagi [10] · Umaira Aziz [11] · Efthimia Karra [11] · Sandip Ghosh [7] · Wasim Hanif [7] · Amy E. Edwards [12] · Mansoor Zafar [13] · Umesh Dashora [13] · Kinga A. Vámai [2,14] · Jim Davies [2,15] · Sarah H. Wild [16] · Emma G. Wilmot [17,18] · David Webb [19] · Kamlesh Khunti [19] · Rustam Rea [1,2] · on behalf of the ABCD Covid-19 audit group

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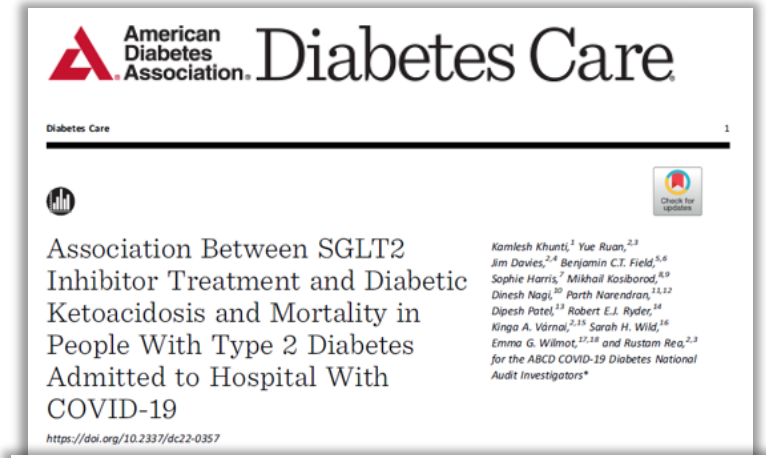
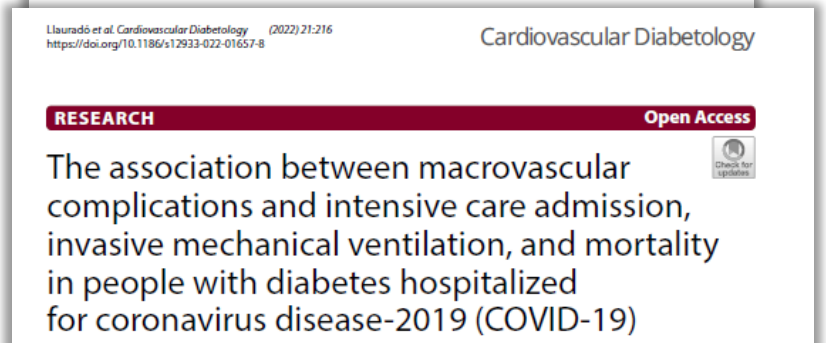

American Diabetes Association. Diabetes Care

Diabetes Care 1

Association Between SGLT2 Inhibitor Treatment and Diabetic Ketoacidosis and Mortality in People With Type 2 Diabetes Admitted to Hospital With COVID-19

*Kamlesh Khunti,[1] Yue Ruan,[2,3] Jim Davies,[2,4] Benjamin C.T. Field,[5,6] Sophie Harris,[7] Mikhail Kosiborod,[8,9] Dinesh Nagi,[10] Parth Narendran,[11,12] Dipesh Patel,[13] Robert E.J. Ryder,[14] Kinga A. Várnai,[2,15] Sarah H. Wild,[16] Emma G. Wilmot,[17,18] and Rustam Rea,[2,3] for the ABCD COVID-19 Diabetes National Audit Investigators**

https://doi.org/10.2337/dc22-0357


Llauradó et al. Cardiovascular Diabetology (2022) 21:216
https://doi.org/10.1186/s12933-022-01657-8

Cardiovascular Diabetology

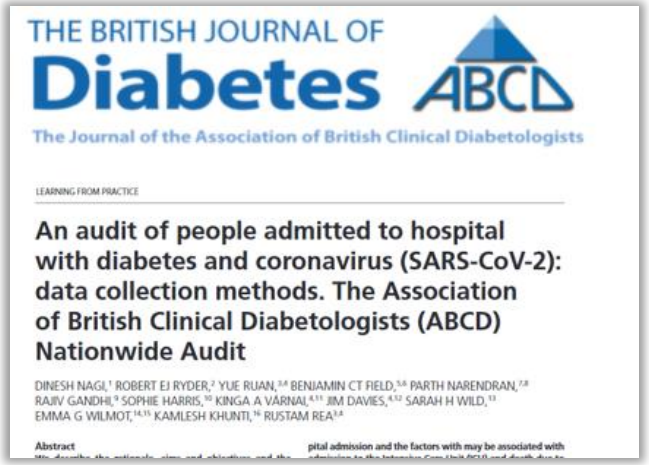
RESEARCH Open Access

The association between macrovascular complications and intensive care admission, invasive mechanical ventilation, and mortality in people with diabetes hospitalized for coronavirus disease-2019 (COVID-19)

- 3542 people with diabetes and COVID admitted to 42 NHS hospitals across the UK
- Extended to a collaboration between UK, France and Spain and one between UK, France and New York
- 10 or 11 published papers!

ABCD
Association of British Clinical Diabetologists

ABCD COVID-19 and Diabetes audit


THE BRITISH JOURNAL OF Diabetes ABCD

The Journal of the Association of British Clinical Diabetologists

LEARNING FROM PRACTICE

An audit of people admitted to hospital with diabetes and coronavirus (SARS-CoV-2): data collection methods. The Association of British Clinical Diabetologists (ABCD) Nationwide Audit

DINESH NAGI,[1] ROBERT EJ RYDER,[2] YUE RUAN,[3,4] BENJAMIN CT FIELD,[5,6] PARTH NARENDRAN,[7,8] RAJIV GANDHI,[9] SOPHIE HARRIS,[10] KINGA A VÁRNAI,[4,11] JIM DAVIES,[4,12] SARAH H WILD,[13] EMMA G WILMOT,[14,15] KAMLESH KHUNTI,[16] RUSTAM REA[3,4]

Abstract


Diabetes & Metabolic Syndrome: Clinical Research & Reviews 16 (2022) 102484

Contents lists available at ScienceDirect

Diabetes & Metabolic Syndrome: Clinical Research & Reviews

journal homepage: www.elsevier.com/locate/dsx

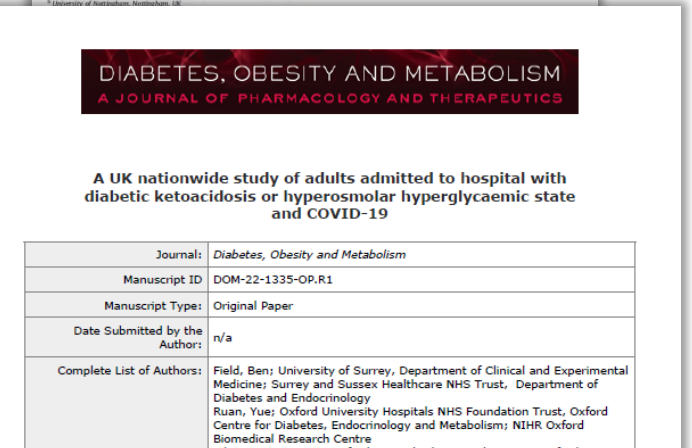
Original Article

Association of statin and/or renin-angiotensin-aldosterone system modulating therapy with mortality in adults with diabetes admitted to hospital with COVID-19: A retrospective multicentre European study

Sophie Harris [a,*,1], Yue Ruan [g,h,1], Sarah H. Wild [c,1], Matthieu Wargny [d,r], Samy Hadjadj [d], Béatrice Delasalle [f], Maëva Saignes [f], Robert EJ. Ryder [k], Benjamin CT. Field [m,n], Parth Narendran [p,q], Francesco Zaccardi [i], Emma G. Wilmot [a,b], Bogdan Vlacho [e], Gemma Llauradó [j,l], Didac Mauricio [j,l], Dinesh Nagi [q], Dipesh Patel [s], Kinga A. Várnai [h,w], Jim Davies [h,x], Pierre Gourdy [o], Bertrand Cariou [d], Rustam Rea [g,h,1], Kamlesh Khunti [t,2], for the CORONADO, the ABCD COVID-19 diabetes national audit and HM Hospitales investigators

[a] Diabetes Department, University Hospitals of Derby and Burton NHS FT, Derby, UK

[b] University of Nottingham, Nottingham, UK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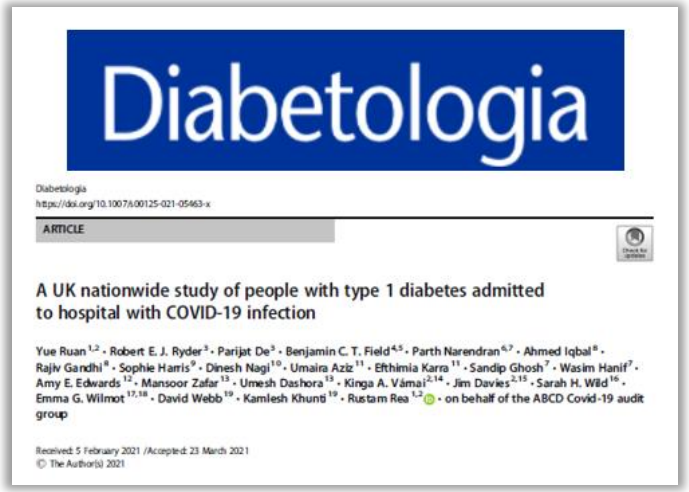
Complete List of Authors:	Field, Ben; University of Surrey, Department of Clinical and Experimental Medicine; Surrey and Sussex Healthcare NHS Trust, Department of Diabetes and Endocrinology Ruan, Yue; Oxford University Hospitals NHS Foundation Trust, Oxford Centre for Diabetes, Endocrinology and Metabolism; NIHR Oxford Biomedical Research Centre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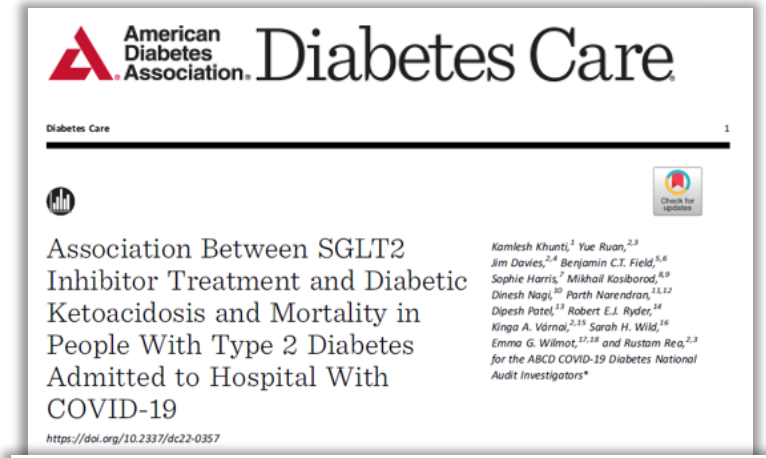
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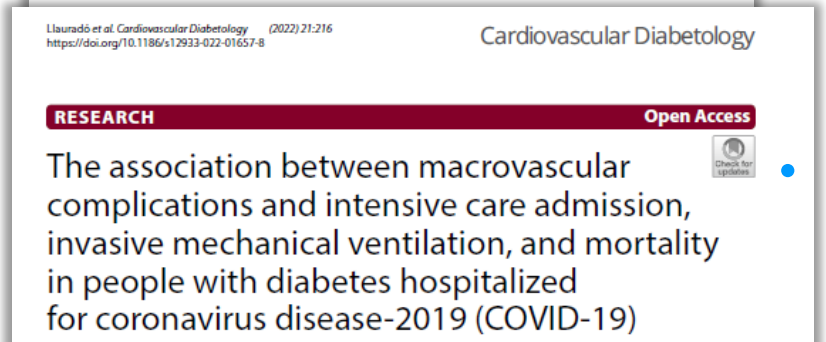
*Kamlesh Khunti,[1] Yue Ruan,[2,3] Jim Davies,[2,4] Benjamin C.T. Field,[5,6] Sophie Harris,[7] Mikhail Kosiborod,[8,9] Dinesh Nagi,[10] Parth Narendran,[11,12] Dipesh Patel,[13] Robert E.J. Ryder,[14] Kinga A. Várnai,[2,15] Sarah H. Wild,[16] Emma G. Wilmot,[17,18] and Rustam Rea,[2,3] for the ABCD COVID-19 Diabetes National Audit Investigators**


Llauradó et al. Cardiovascular Diabetology (2022) 21:216
https://doi.org/10.1186/s12933-022-01657-8

Cardiovascular Diabetology

RESEARCH Open Access

The association between macrovascular complications and intensive care admission, invasive mechanical ventilation, and mortality in people with diabetes hospitalized for coronavirus disease-2019 (COVID-19)

- Risk of severe COVID-19 is reassuringly very low in people with type 1 diabetes who are under 55 years of age without microvascular or macrovascular disease
- No evidence of increased risk of DKA or hospital mortality associated with prescription of SGLT2 inhibitors
- Microvascular burden is associated with an increased risk of death in patients hospitalized for COVID-19
- Hospitalisation with COVID-19 and adjudicated DKA is four times more common than HHS but both associate with substantial mortality
- In people with diabetes mellitus hospitalized for COVID-19 previous macrovascular disease is associated with higher mortality

TESTOSTERONE DEFICIENCY IN MEN WITH TYPE 2 DIABETES

- High prevalence - 40% of men with type 2 diabetes have symptomatic testosterone deficiency

Kapoor D, et al. Diabetes Care 2007;30:911-917

Association of British Clinical Diabetologists

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TESTOSTERONE DEFICIENCY IN MEN WITH TYPE 2 DIABETES

- High prevalence - 40% of men with type 2 diabetes have symptomatic testosterone deficiency
- Asking about erectile dysfunction should be part of routine annual review in all men with diabetes

Association of British Clinical Diabetologists

TESTOSTERONE DEFICIENCY IN MEN WITH TYPE 2 DIABETES

- High prevalence - 40% of men with type 2 diabetes have symptomatic testosterone deficiency
- Asking about erectile dysfunction should be part of routine annual review in all men with diabetes
- Testosterone replacement has been shown to:
  - Improve insulin resistance
  - Lower HbA1c
  - Lower cholesterol
  - Reduce body weight
  - Reduce mortality

Kapoor D, et al. Eur J Endocrinol 2006;154:899-906
Dhindsa S et al. Diabetes Care 2016;39:82-91
Hackett G et al, J Sexual Medicine 2013;10:1612-1627
Jones TH et al. Diabetes Care 2011;34:828-837
Groti K et al. The Aging Male 2018;21:158-169
Haider KS et al. Diab Obes Metab 2020;22:2055-2068

ABCD worldwide audit of Testosterone and Diabetes


59TH ANNUAL MEETING
EUROPEAN ASSOCIATION FOR THE STUDY OF DIABETES
#EASD2023
EASD 2023
2-6 Oct
Hamburg

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Activity: Abstract
Current Date/Time: 4/21/2023 5:58:02 AM

Testosterone replacement in men with type 2 diabetes lowers HbA_{1c}: ABCD worldwide audit

Author Block: H. Jones[1], K. Darzy[2], R. Troke[2], U. Dashora[3], A. Haider[4], R. Ryder[5];
[1]Diabetes and Endocrinology, Barnsley Hospital, Barnsley, UK, [2]Diabetes and Endocrinology, Lister Hospital, Stevenage, UK, [3]Diabetes and Endocrinology, Conquest Hospital, Hastings, UK, [4]Urology private practice, Bremerhaven, Germany, [5]Diabetes and Endocrinology, Barnsley Hospital, Sandwell and West Birmingham Hospitals, UK.

Abstract:
Background and aims: Testosterone replacement therapy (TRT) has been reported to reduce insulin resistance, HbA1c, obesity and mortality and improve quality of life, sexual function. The Association of British Clinical Diabetologists (ABCD) has set up as part of their audit programme a Worldwide Audit of Testosterone in Men with Type 2 Diabetes. The aim of the audit is to determine the real world benefits and safety of TRT on symptoms, glycaemic control, obesity, other cardiometabolic parameters and on cardiovascular events and diabetes complications. Individual centres that take part can audit their own clinical practice.

- From mean baseline HBA1c of 71 mmol/mol HbA1c fell by:
  - 5 mmol/mol by 3 months
  - 10 mmol/mol by 12 months
  - 15 mmol/mol by 24 months
- The fact that HbA1c continues to decrease over time is likely to be due to the ongoing effect of testosterone on fat reduction

Scheduled for presentation at EASD 2023

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ABCD EndoBarrier worldwide registry

Fluoropolymer wall

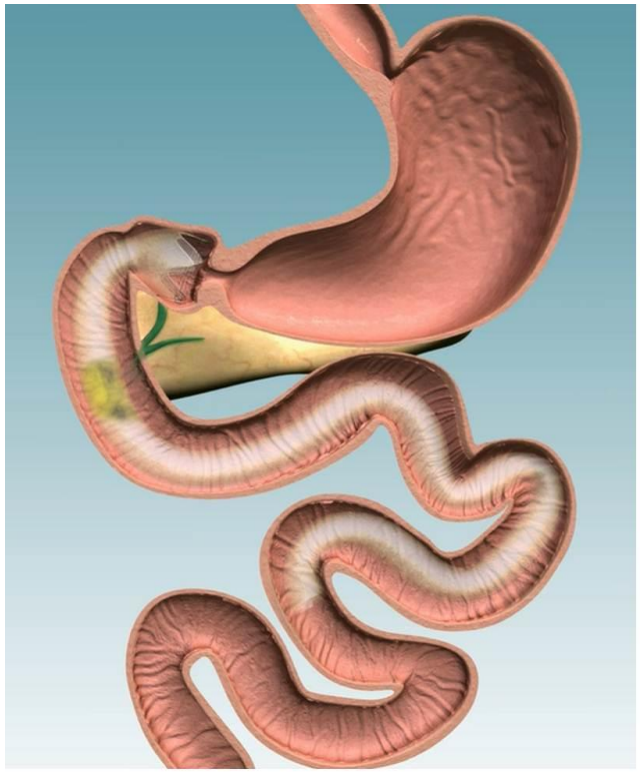
Nitinol Anchor

- 60 cm impermeable sleeve
- Minimally invasive

ABCD EndoBarrier worldwide registry

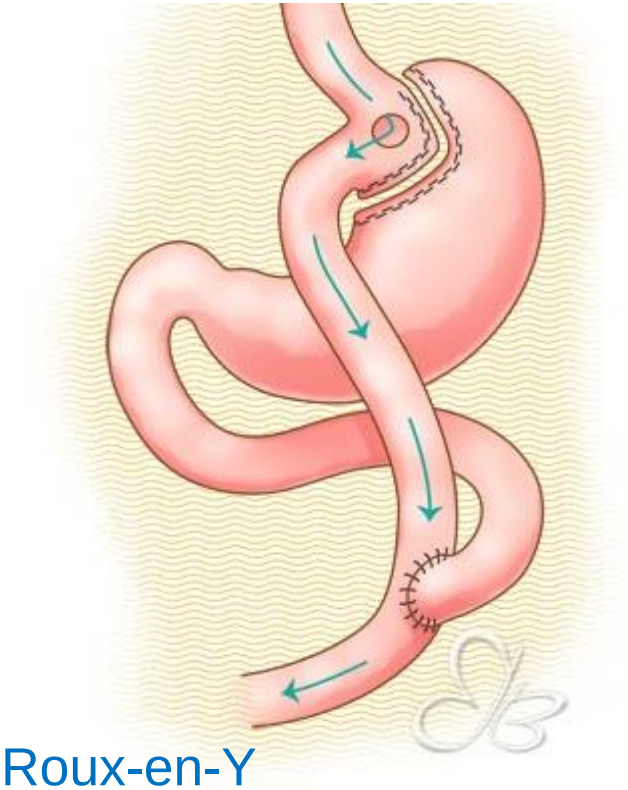
Fluoropolymer wall

Nitinol Anchor



- 60 cm impermeable sleeve
- Minimally invasive

ABCD EndoBarrier worldwide registry

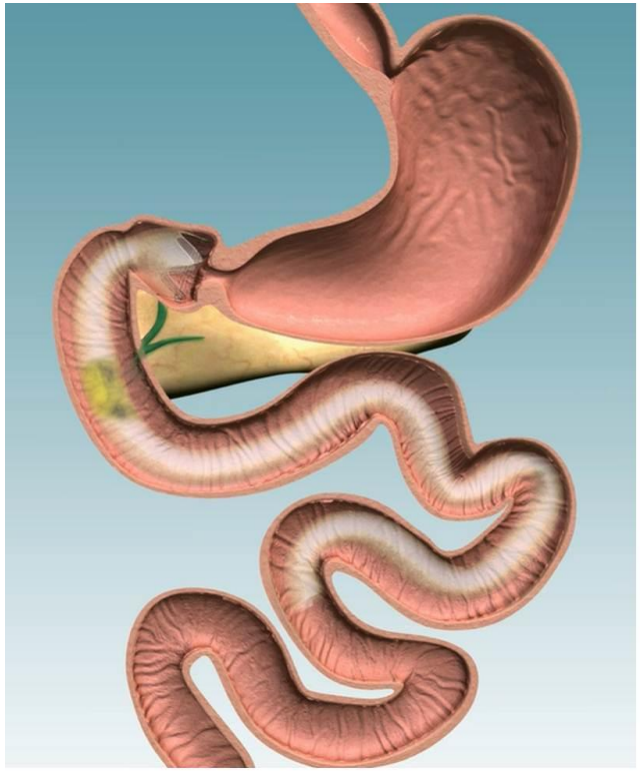


Roux-en-Y gastric bypass surgery

Fluoropolymer wall

Nitinol Anchor

- 60 cm impermeable sleeve
- Minimally invasive



Association of British Clinical Diabetologists

ABCD EndoBarrier worldwide registry

Diabetes Care Volume 46, April 2023 e89

Check for updates

Endoscopic Duodenal-Jejunal Bypass Liner Treatment for Type 2 Diabetes and Obesity: Glycemic and Cardiovascular Disease Risk Factor Improvements in 1,022 Patients Treated Worldwide

Diabetes Care 2023;46:e89–e91 | https://doi.org/10.2337/dc22-1952

Robert E.J. Ryder,[1] Katharina Laubner,[2] Marek Benes,[3] Martin Haluzik,[3] Lynne Munro,[4] Harry Frydenberg,[4] Julian P. Teare,[5] Aruchuna Ruban,[5] Sigal Fishman,[6] Erwin Santo,[6] Rainer Stengel,[7] Charlotte De Jonge,[8,9,10] Jan W. Greve,[11,12] Ricardo V. Cohen,[13] Cristina M. Aboud,[13] Gerald J. Holtmann,[14] Graeme Rich,[15] Jess J. McMaster,[14] Tadej Battelino,[16,17] Primoz Kotnik,[17] James P. Byrne,[18] John C. Mason,[19] Justin Bessell,[20] Jeanine Bascomb,[21] Lillian Kow,[21] Janes Collins,[22] Jacob Chisholm,[22] Peter N. Pferschy,[23] Harald Sourij,[23] Melissa L. Cull,[1] Melanie C. Wyres,[1] Russell Drummond,[24] Barbara McGowan,[25] Stephanie A. Amiel,[26] Mahi Yadagiri,[1] Piya Sen Gupta,[1,25] Jens Aberle,[27] and Jochen Seufert[2]

There is a worldwide pandemic of type 2 diabetes (T2D) and obesity (1). In clinical practice, many patients with obesity have poor glycemic management despite diet and lifestyle advice and maximal medications (2–4). In this situation, Roux-en-Y gastric bypass is highly effective, and increased use of bariatric surgery has been recommended (2). Nevertheless, it is an invasive and irreversible surgical procedure. EndoBarrier (GI Dynamics, Boston, MA), also known as duodenal-jejunal bypass liner, is a 60-cm impermeable

endoscopically into the upper part of the small intestine (2–4), left in place for up to 1 year, and then removed endoscopically. The duodenal-jejunal bypass liner was developed to mimic the proposed small-bowel mechanisms of Roux-en-Y gastric bypass (2–4) while being less invasive. In Europe in 2017, approval for use (certificate of Conformité Européenne, or CE mark) of EndoBarrier was not renewed for reasons that are not entirely clear (3,4). As over 3,000 patients have been treated with EndoBarrier

secure, online registry was established by the Association of British Clinical Diabetologists (ABCD) for the collection of safety and efficacy data of EndoBarrier-treated patients worldwide.

By October 2022, data had been entered on 1,022 EndoBarrier-treated patients (mean ± SD age 51.3 ± 11.4 years, 52.5% male, 84.9% with diabetes, mean ± SD BMI 41.1 ± 8.7 kg/m^2) from 34 centers in 10 countries. For those with both baseline and time-of-removal data, EndoBarrier treatment was associated with consider-

- Registry data published in Diabetes Care, April 2023

Ryder et al. Diabetes Care 2023;46:e89–e91

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ABCD EndoBarrier worldwide registry

Baseline characteristics

Parameter	n=1022
Age (years)	51.3±11.2
Sex (% male)	52.5
BMI (kg/m^2)	41.1±8.7
Diabetes (%)	84.9

ABCD EndoBarrier worldwide registry

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Association of British Clinical Diabetologists

ABCD EndoBarrier worldwide registry

Impact of EndoBarrier

Parameter	n	Baseline	EndoBarrier Explant	Difference	P-value
Weight (kg)	811	120.2±25.3	106.9±23.8	-13.3±9.7	<0.001
HbA1c (mmol/mol)	646	67.6±19.8	53.9±13.9	-13.7±15.9	<0.001
HbA1c (%)	646	8.3±1.8	7.1±1.3	-1.3±1.5	<0.001
Systolic BP (mmHg)	448	135.7±18.0	129.5±17.0	-6.3±19.2	<0.001
Cholesterol (mmol/L)	467	4.8±1.2	4.2±1.0	0.6±1.03	<0.001

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ABCD EndoBarrier worldwide registry

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Diabetes (%)	84.9

ABCD EndoBarrier worldwide registry

HbA1c response according to baseline HbA1c

HbA1c Range (%)	n	Baseline	At Removal	Difference	P value
All HbA1c	646	8.3±1.8	7.1±1.3	-1.3±1.5	<0.001
All HbA1c ≥ 7	506	9.0±1.5	7.4±1.2	-1.6±1.5	<0.001
All HbA1c ≥ 8	365	9.5±1.4	7.6±1.2	-1.9±1.5	<0.001
All HbA1c ≥ 9	207	10.4±1.3	7.9±1.3	-2.5±1.6	<0.001
HbA1c ≥ 10	111	11.2±1.2	8.0±1.5	-3.2±1.7	<0.001

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ABCD EndoBarrier worldwide registry

HbA1c response according to baseline HbA1c

HbA1c Range (mmol/mol)	n	Baseline	At Removal	Difference	P value
All HbA1c	646	67.6±19.8	53.9±13.9	-13.7±15.9	<0.001
All HbA1c ≥ 53	506	74.6±16.3	57.6±12.9	-17.0±16.3	<0.001
All HbA1c ≥ 64	365	80.8±15.0	60.1±13.4	-20.7±16.9	<0.001
All HbA1c ≥ 75	207	90.0±13.9	63.0±14.4	-27.0±18.0	<0.001
All HbA1c ≥ 86	111	99.1±13.2	64.1±15.9	-34.9±18.1	<0.001

ABCD
Association of British Clinical Diabetologists

Latest from the EndoBarrier Worldwide Registry

American Diabetes Association.
83RD SCIENTIFIC SESSIONS
SAN DIEGO, CA | JUNE 23–26, 2023

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Activity: Abstract
Current Date/Time: 12/27/2022 6:30:58 AM

Comparing 9- vs 12-Month Implantation in the Worldwide EndoBarrier (EB) Registry

Author Block: ROBERT E.J. RYDER, MAHENDER YADAGIRI, LYNNE MUNRO, HARRY FRYDENBERG, SIGAL FISHMAN, JAMES P. BYRNE, JULIAN P. TEARE, CHARLOTTE DE JONGE, JAN WILLEM GREVE, JESSICA J. MCMASTER, JACOB CHISHOLM, LILIAN KOW, JOHN C. MASON, RICARDO V. COHEN, PIYA SEN GUPTA, *Birmingham, United Kingdom, Richmond, Australia, Tel Aviv, Israel, Southampton, United Kingdom, London, United Kingdom, Eindhoven, Netherlands, Heerlen, Netherlands, Brisbane, Australia, Adelaide, Australia, Manchester, United Kingdom, Sao Paulo, Brazil*

Abstract:
Uncertainty exists re risk:benefit of proximal intestinal exclusion with EB, a novel endoscopic duodenal jejunal liner device for obesity, both with and without diabetes. In view of this, during 2017, an independent, secure, on line registry was established under the auspices of the Association of British Clinical Diabetologists, for the collection of safety and efficacy data worldwide. As of December 2022, data had been entered on 1022 patients, of whom 195 (age 51.6±10.3 years, 53% male, 81% white ethnicity, BMI 39.9±6.9kg/m^2) had both 9- and 12-month data entered. EB had considerable impact on weight and HbA1c (Table). There was no difference between the mean±SD reduction in HbA1c or weight at 9- vs 12-months (HbA1c: 1.39±1.67% vs 1.38±1.66% (p=0.98); weight: 11.7±8.3kg vs 12.0±8.3kg (p=0.44). The higher the HbA1c the greater the fall but again no difference between 9- and 12-months (Table). In the full registry, 43/1022 (4.2%) experienced serious adverse events (SAE). 15/43 (34.9%) SAE would have been avoided by removal at 9-months (9 liver abscess, 4 GI bleed, one cholecystitis). It was particularly noteworthy that 9/13 (69.2%) liver abscess SAEs would have been avoided by removal at 9-months. This international data from the EB registry suggests that the benefits of EB are achieved in 9-months and a reduction in the recommended implantation period from 12- to 9-months would reduce SAEs, especially the liver abscess SAE.

Table. Impact of EndoBarrier on weight and HbA1c. The higher the initial HbA1c, the greater the reduction. There was no difference between the reduction in weight or HbA1c at 9-months compared to 12-months. Data from 195 patients from 11 centres in 5 countries (Australia, Brazil, United Kingdom, Israel and Netherlands). Data from the Worldwide EndoBarrier Registry.

Parameter	n	Baseline	9-months	12-months	Difference 9-months vs baseline	Difference 12-months vs baseline	P-value baseline vs 9-months	P-value baseline vs 12-months	P-value difference 9- vs 12-months
Weight (kg)	195	115.3±22.7	103.4±22.1	103.1±23.0	-11.7±8.3	-12.0±8.3	<0.001	<0.001	0.44
All HbA1c (%)	140	8.8±1.6	7.8±1.2	7.8±1.2	-1.4±1.6	-1.4±1.6	<0.001	<0.001	0.98
HbA1c ≥ 7%	127	9.0±1.5	7.4±1.2	7.4±1.2	-1.6±1.6	-1.6±1.5	<0.001	<0.001	0.86
HbA1c ≥ 8%	91	9.6±1.3	7.6±1.3	7.6±1.3	-2.0±1.5	-2.0±1.5	<0.001	<0.001	0.96
HbA1c ≥ 9%	59	10.4±1.2	7.8±1.3	7.8±1.4	-2.6±1.6	-2.6±1.9	<0.001	<0.001	0.87
HbA1c ≥ 10%	31	11.2±0.9	8.1±1.6	8.0±1.5	-3.1±1.7	-3.2±1.5	<0.001	<0.001	0.24

Category (Complete): 23-B Obesity—Human
Presentation Preference (Complete): Oral Preferred
Financial Support (Complete):
*** ADA Support**: No
Supported by: : Association of British Clinical Diabetologists

- As of May 2023, data had been entered on 1068 EndoBarrier treated patients, of whom 196 had both 9- and 12-month data entered
- Reducing the implantation period from 12-months to 9-months resulted in:
  - No significant difference in weight loss or in the improvement in HbA1c
  - 33.3% reduction in SAE
- It was particularly noteworthy that 64.3% liver abscess SAE would have been avoided by removal at 9-months
- These data support a change in the recommended implantation period for EndoBarrier from 12-months to 9-months

Ryder et al. Presented ADA 83rd Scientific Sessions, San Diego, June 2023

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Acknowledgements

Dr Emma Wilmot – ABCD deputy clinical audits lead

Dr Tom Crabtree – ABCD audits research fellow

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Dr Harshal Deshmukh – research fellow, ABCD FreeStyle Libre audit

Dr Rustam Rea – clinical lead, ABCD COVID-19 and diabetes audit

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The ABCD Exec, the Gila monster

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The ABCD Exec, the Gila monster, and …..

Thank you to all the audit contributors!

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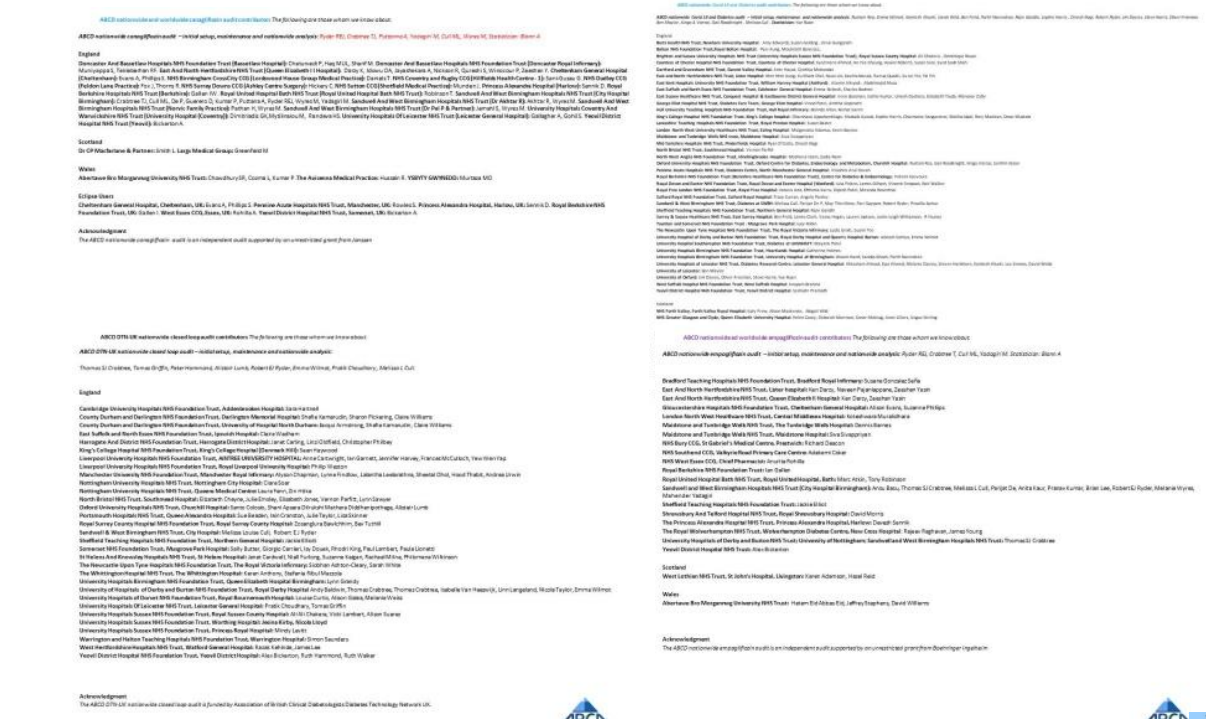
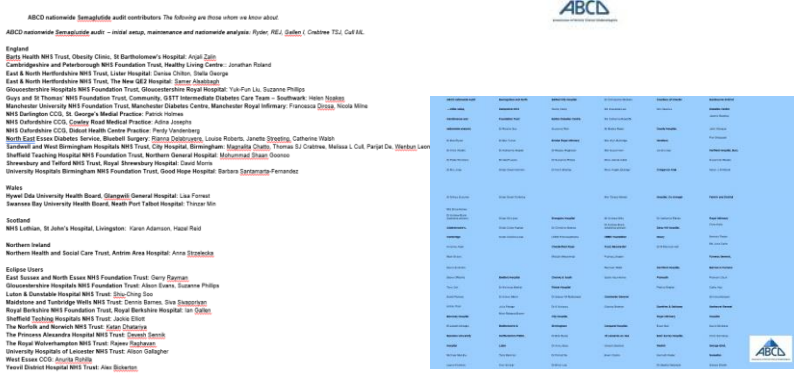
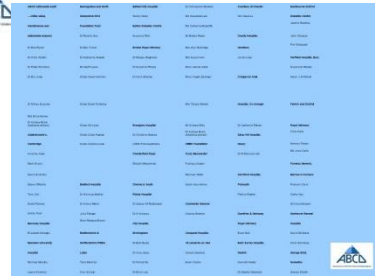
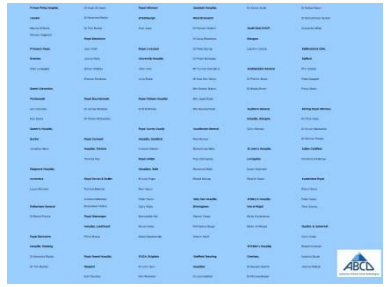
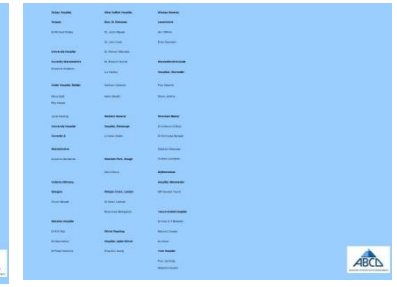
ABCD nationwide & Worldwide audits – initial setup, maintenance and nationwide analysis: *Ryder, REJ, Cull ML.*











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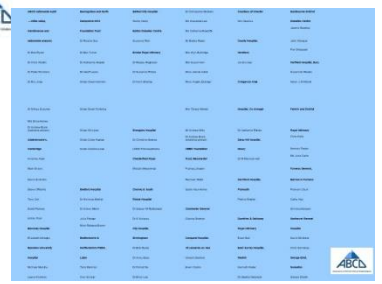

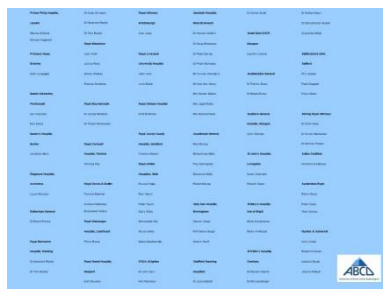

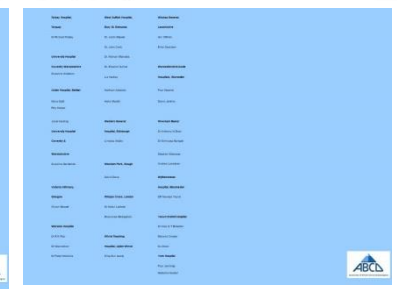

Please help with these audits:

- Testosterone deficiency in men with type 2 diabetes
- Oral semaglutide

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